

Contents

OVERVIEW AND ORGANIZATION	2
Table 1. List of Commenters	4
LIST OF ACRONYMS/ABBREVIATIONS	5
COMMENT RESPONSES	6
African American Caucus of the League of California Cities	6
Ms. Cheryl Brown (Former Assembly Member)	6
18 Environmental Coalitions and Organizations	6
Ms. Joni Arends	7
California Council for Environmental and Economic Balance	8
California Manufacturers and Technology Association	12
City of Compton	23
Committee to Bridge the Gap	25
Fresh Air Vallejo	28
U.S. Department of Defense	28
Fort Ord Environmental Justice Network	28
Latham & Watkins, LLP	28
Physicians for Social Responsibility-Los Angeles	34
Mr. Michael Rincon	35
Rocketdyne Cleanup Coalition	39
Ms. Laura Rosenberger Haider	42
Rootskeeper	42
Seven Commerce Organizations	42
Southern California Federation of Scientists	43
REFERENCES	44

OVERVIEW AND ORGANIZATION

This attachment (Attachment 2) to the Final Statement of Reasons (FSOR) summarizes, responds to, and addresses the public comments submitted to the Department of Toxic Substances Control (DTSC) on the revised proposed rule titled Toxicity Criteria for Human Health Risk Assessments, Screening Levels and Remediation Goals, during the public comment period that began on April 6, 2018, and ended on April 21, 2018 (“April Proposed Rule”). Attachment 1 to the FSOR provides the comment responses to the public comments on the August 4, 2017 publicly noticed proposed rule (“August Proposed Rule”). Attachment 1 also summarizes rulemaking activities conducted up to the April 6, 2018 release of the April Proposed Rule.

Comment letters were received from the 19 organizations, companies, or individuals identified in Table 1. For tracking purposes, where applicable 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, 18ECO refers to the commenting group “18 Environmental Coalitions and Organizations” and the 18ECO comments are sequentially numbered (e.g., 18ECO-01, 18ECO-02, etc.).

Although received from different parties, comments were essentially identical for six of the commenters. These are:

- 18 Environmental Coalitions and Organizations (18ECO)
- Ms. Joni Arends
- Fort Ord Environmental Justice Network
- Fresh Air Vallejo
- Ms. Laura Rosenberger Haider
- Rootskeeper

Because of this, comments from all these parties are addressed only in responses to 18ECO. Comments received late (on June 13, 2018) from Ms. Cheryl Brown and (on June 14, 2018) from the African American Caucus of the League of California Cities (Caucus) were addressed in a similar way as their comments were essentially the same as those from the City of Compton and so Ms. Brown’s and the Caucus comments are addressed in the responses to the City of Compton comments.

Some commenters on the April Proposed Rule also previously provided comments on the August Proposed Rule. To easily distinguish these separate sets of comments, for these commenters, comments on the April proposed rule are numbered sequentially beginning with the number following the number assigned to the last comment the commenter made on the August Proposed Rule. For example, the California Manufacturers and Technology Association (CMTA) provided 30 comments on the August Proposed Rule. So, their first comment on the April Proposed Rule begins with CMTA-31.

In contrast to the responses to comments on the August Proposed Rule where comments were grouped by “theme,” comments herein on the April Proposed Rule are addressed individually. In other words, for each comment, the comment is briefly summarized and then a response is provided.

DTSC appreciates all comments provided and has carefully reviewed and considered all comments provided to DTSC on the Proposed Rule. However, unless specifically noted otherwise, DTSC has determined that it is not necessary to make some of the revisions to the rule language, as requested in the comment letters for the reasons noted in each response below.

Table 1. List of Commenters

Acronym	Name of Entity	Number of Comments*
n/a	African American Caucus of the League of California Cities	(see COC)
n/a	Ms. Cheryl Brown	(see COC)
18ECO	18 Coalitions and Organizations	3
n/a	Ms. Joni Arends	(see 18ECO)
CCEEB	California Council for Environmental and Economic Balance	7
CMTA	California Manufacturers and Technology Association	31
CBG	Committee to Bridge the Gap	7
COC	City of Compton	8
DOD	U.S. Department of the Navy (Department of Defense)	1
FAV	Fresh Air Vallejo	(see 18ECO)
n/a	Fort Ord Environmental Justice Network	(see 18ECO)
L&W	Latham & Watkins, LLP	1
PSRLA	Physicians for Social Responsibility-Los Angeles	4
RIN	Mr. Michael Rincon	7
RCC	Rocketdyne Cleanup Coalition	8
n/a	Ms. Laura Rosenberger Haider	(see 18ECO)
n/a	Rootskeeper	(see 18ECO)
SCO	Seven Commerce Organizations: Western States Petroleum Association (WSPA) California Manufacturers & Technology Association (CMTA) Western Independent Refiners Association CalChamber Chemical Industry Council of California (CICC) American Chemistry Council (ACC) California Council for Environmental & Economic Balance (CCEEB)	3
SCFS	Southern California Federation of Scientists	2

* = Number of comments in this responses comments on the April Proposed Rule
n/a = Not applicable, no acronym is used herein

LIST OF ACRONYMS/ABBREVIATIONS

§	Section
µg/dL	Microgram per deciliter
µg/m ³	Microgram per cubic meter
APA	Administrative Procedures Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CSFo	Oral Cancer Slope Factor
DOD	Department of Defense
DTSC	Department of Toxic Substances Control
EIR	Environmental Impact Report
EPA	Environmental Protection Agency
FSOR	Final Statement of Reasons
FYR	Five-Year Review
HERO	Human and Ecological Risk Office
HHRA	Human Health Risk Assessment
HSC	Health and Safety Code
IRIS	Integrated Risk Information System
ISOR	Initial Statement of Reasons
IUR	Inhalation Unit Risk
NCP	National Contingency Plan
OEHHA	Office of Environmental Health Hazard Assessment
OSWER	Office of Solid Waste and Emergency Response
PCE	Perchloroethylene or Tetrachloroethylene
PPRTV	Professional Peer-Reviewed Toxicity Values
RAGS	Risk Assessment Guidance for Superfund
REL	Reference Exposure Level
RfC	Reference Concentration
RTCs	Response to Comments
TCE	Trichloroethylene
U.S.	United States

COMMENT RESPONSES

African American Caucus of the League of California Cities

The Caucus' comments were received on June 14, 2018 and are essentially the same as those provided by the City of Compton. To avoid redundancy, the Caucus' comments are addressed by the responses to the comments from the City of Compton below.

Ms. Cheryl Brown (Former Assembly Member)

Ms. Brown's comments were received on June 13, 2018 and are essentially the same as those provided by the City of Compton. To avoid redundancy, Ms. Brown's comments are addressed by the responses to the comments from the City of Compton below.

18 Environmental Coalitions and Organizations

Below are responses to comments from the group identified as "18 Environmental Coalitions and Organizations" (18ECO).

Comment 18ECO-01. The commenter states that in selecting toxicity criteria, the rule should give precedence to the most protective available toxicity criteria of the various criteria sources.

Response. DTSC has considered this recommendation but respectfully disagrees. The protectiveness of toxicity criteria must be based on sound science and satisfy the statutory requirements regarding peer review and scientific quality, as identified in this proposed rule. As explained in the Initial Statement of Reasons (ISOR) and under the General Comment Category "Best Available Science" in DTSC's response to comments on the August Proposed Rule ("Attachment 1" to this FSOR), toxicity criteria must meet the best available science requirements provided in California Health and Safety Code (HSC) §25356.1.5 and HSC §57004 and be consistent with federal and state guidance to qualify for inclusion in Appendix I for use in risk assessments for hazardous waste and substance release cleanup sites in California.

Comment 18ECO-02. The commenter states that the Office of Environmental Health Hazard Assessment (OEHHA), and not DTSC, determines toxicity criteria for contaminants, and that the rule should give precedence to the most protective available toxicity criteria.

Response. While DTSC agrees that OEHHA has specialized and very pertinent expertise regarding toxicity criteria and has a leading role for developing toxicity criteria for California, it is not correct that every OEHHA toxicity criteria value satisfies the statutory requirements necessary to be included in this proposed rule. As DTSC responded under Comment Category "Best Available Science" in Attachment 1, while

OEHHA develops California’s toxicity criteria for contaminants, DTSC is responsible for determining the appropriate toxicity criteria for use at hazardous waste and substance release cleanup sites in California.

However, to make these determinations, DTSC closely collaborated with OEHHA to identify those criteria that meet HSC §25356.1.5 and §57004, and are consistent with United States Environmental Protection Agency (U.S. EPA) and state guidance. DTSC has attached Supplement 1 at the end of these comment responses to provide more detailed explanation on why some OEHHA values (that are more stringent than Integrated Risk Information System [IRIS] values) are not provided in Appendix I to the rule. Supplement 1 is a “working draft table” DTSC used to develop the list of values in Appendix I. Supplement 1 contains the list of contaminants that were in the revised April Proposed Rule (that was publicly noticed on April 6, 2018). Since then, at DTSC’s request, OEHHA confirmed for DTSC (in blue and green shading in Supplement 1) that those values that have undergone peer review through the Scientific Review Panel (SRP) pursuant to HSC §57004. These blue and green shaded values are published in the final rule. Additionally, the final column of the table provides the justification for the toxicity criteria that have been removed from Appendix I.

Finally, as discussed in the response to 18ECO-01 above, application of best available science takes precedence in selecting appropriate toxicity criteria, and making protectiveness the sole determinant for appropriate toxicity criteria under this rule would conflict with existing law including but not limited to HSC §25356.1.5 on risk assessments.

Comment 18ECO-03. The commenter states that references to land use should not be included in the proposed rule. Alternately, if land use is included, it should be referenced as “anticipated land use of the site and surrounding area.”

Response. In the rule, the term “reasonably anticipated future land uses” is used in the definition of Remediation Goal as an example of one of many factors to be considered when selecting the remediation goal. Accordingly, DTSC has made no change to the rule as this term has no bearing on the selection of toxicity criteria and is consistent with U.S. EPA Office of Solid Waste and Emergency Response (OSWER) Directive 9355.7-04. Pursuant to the U.S. National Contingency Plan (NCP), reasonably anticipated land use of the site is considered when selecting remediation goals which is the only reason this term was included in the definition.

Ms. Joni Arends

While received separately, Ms. Joni Arends’ comments are essentially the same as those from “18 Environmental Coalitions and Organizations.” Accordingly, Ms. Arends comments are addressed by the responses to the comments from “18 Environmental Coalitions and Organizations” above.

California Council for Environmental and Economic Balance

Below are responses to comments from the California Council for Environmental and Economic Balance (CCEEB). CCEEB also provided comments as part of the Seven Commerce Organizations (SCO). SCO comments are addressed later in this Attachment. Finally, CCEEB also provided 11 comments on the August Proposed Rule, therefore the comment numbers below begin with CCEEB-12.

Comment CCEEB-12. The commenter questions the reason for the proposed rule, and contends that this rule is unnecessary.

Response. DTSC believes that it is valuable and necessary to formally adopt a single statewide set of toxicity criteria to protect human health from hazardous substance releases in the environment where the criteria meet statutory standards for adoption. As specified in the ISOR and the rule text, the purpose of the rule is to formally adopt certain toxicity criteria for all human health-based risk assessments, human health risk-based screening levels, and human health risk-based remediation goals at hazardous waste and substance release cleanup sites in California. For a more thorough discussion of this, please see page 9 in the ISOR, and DTSC's response in the Comment Categories "Legal Considerations," "Changing Present Practice-OEHHA Values Not Required," and "Application at Non-DTSC Lead Sites" in Attachment 1.

Comment CCEEB-13. The commenter states that the proposed rule does not take into account "best available science" and is inconsistent with HSC §116365(c)(1).

Response. DTSC toxicology staff have conferred with their OEHHA counterparts and have reviewed the materials regarding methods, models, and studies on which the IRIS and OEHHA values were issued. As explained in the ISOR and in DTSC's responses in the General Comment Category "Best Available Science" in Attachment 1, the proposed rule specifically applies best available science in accordance with HSC §25356.1.5 and §57004. Similarly, as explained in DTSC's response for the Comment Category "Best Available Science" in Attachment 1, HSC §25356.1.5 contains nearly identical language to HSC §116365(c)(1) regarding use of the most current scientific principles, practices, and methods used by experts to achieve protection of public health such that further revision of the rule is not necessary to accomplish the commenter's request. Furthermore, HSC §116365(c)(1), applies to the Water Board and not to DTSC. As discussed in the ISOR, DTSC believes the rule properly implements HSC §25356.1.5 and is therefore consistent with HSC §116365(c)(1) and other similar statutory requirements and, as a result, disagrees with the commenter's statement.

Comment CCEEB-14. The commenter requests that DTSC, as part of the rulemaking, provide the detailed process for selecting toxicity criteria under proposed §69021(c).

Response. DTSC does not believe that it is necessary to add the detailed process to the rule language. The process is rule implementation and is not appropriate to be part of the rule language itself, which, as explained in the responses under "Toxicity Criteria

Approval – 69021(c)” in Attachment 1, will be provided in a new forthcoming Human and Ecological Risk Office (HERO) Human Health Risk Assessment (HHRA) Note.

In addition, please note that DTSC intends to continue its existing and historical practice for reviewing §69021(c) toxicity values in risk assessments submitted for DTSC approval. The historical practice has been for responsible parties to propose a value for use in a particular site’s risk assessment, then obtain DTSC HERO review and approval, which is based on best available science consistent with HSC §25356.1.5. The toxicity criteria selected under §69021(c) will not necessarily meet all the conditions under HSC §25356.1.5 and §57004 but will represent the best available toxicity criteria available at that time, pending subsequent OEHHA or U.S. EPA IRIS development and adoption or issuance of new toxicity criteria for that contaminant. Also, please refer to the additional information as described in the FSOR.

As a convenience and for common reference, when such “other source” values are identified in the course of various site work, whether through currently available values or newly developed site-specific values, DTSC will include these values into the forthcoming HERO HHRA Note and make that document available online.

Comment CCEEB-15. The commenter states that the proposed rule documents lack clarity on the process and associated time requirement for DTSC to “approve” toxicity criteria under proposed HSC §69021(c). The commenter also requested that an Economic and Fiscal Impact Analysis be performed for potential project delays associated with implementing §69021(c).

Response. As explained in DTSC’s response for the Comment Category “Toxicity Criteria Approval-§69021(c)” in Attachment 1, §69021(c) reflects current practice for using the available “other” sources of toxicity criteria. Selected values will be listed in a forthcoming HERO HHRA Note that will be available on DTSC’s public website for reference. Currently, for contaminants without toxicity criteria in Appendix I or IRIS, the recommended toxicity criteria are listed in the U.S. EPA regional screening levels or (DTSC) HERO HHRA Note 3. A responsible party typically uses this value in the draft risk assessment, then submits that document to DTSC through the regular document review process for cleanup under DTSC oversight. A responsible party may propose another value for use and would need to justify their choice as being at least as scientifically sound and protective as any “other” source in §69021(c) that DTSC had previously used. These same values are used when DTSC is conducting state-funded site cleanups.

The new HHRA Note which will be released following approval of the proposed rule is informational and provides a ready reference of recommended values; it is not part of this proposed rule. For any toxicity criteria not listed in the new HERO HHRA Note, the toxicity criteria will be determined on a project-specific need consistent with DTSC’s current practice and, as explained in the FSOR, will result in no new project delays associated with the proposed rule. As previously explained in the response for Comment Category “Financial Consideration” in Attachment 1, there will be no fiscal impact to responsible parties as a result of the implementation of the proposed rule, as

the proposed rule's process is the same as existing and historical practice. With no change in practice, there will be no new financial impact in implementing proposed §69021(c).

Comment CCEEB-16. The commenter requests that the proposed rule include a statement that the rule “does not change the risk management range for establishing remediation goals consistent with the NCP, expanding on the point to indicate the allowed risk management range remains 1×10^{-6} to 1×10^{-4} based on site specific and other factors,” and that Chapters 5, 6.5, and 6.82 and HSC §25356.1.5(d) be added to proposed §69022(c).

Response. The commenter is requesting informative statements without regulatory content be added to the rule text. Inclusion of this language is contrary to the accepted content for formal rule text. The proposed rule's intent is clear on face value which is the selection of appropriate toxicity criteria for use in human health risk assessments and setting human health risk-based screening levels and human health risk-based remediation goals. The rule is consistent with the NCP, and cleanup levels under CERCLA will continue to be developed in accordance with the NCP. To further address this concern, DTSC will provide additional guidance and outreach on implementing the rule and which will reiterate that the rule neither requires nor prohibits the remediation goal from being set at the screening level for any site or contaminant. This is consistent with DTSC's present practice of setting risk-based remediation goals as noted in the ISOR and FSOR. Furthermore, as explained in the response in the Comment Category “Reference Additional Health and Safety Code Chapters” in Attachment 1, DTSC does not believe that it is appropriate to add the requested Chapter additions for the specified reasons. Finally, the existing reference to §25356.1.5 already includes §25356.1.5(d), so citation to subsection (d) is not necessary.

Also, please see specific responses to comments CMTA-57, COC-07, L&W-06.4 and SCO-2.

Comment CCEEB-17. The commenter states that the proposed rule does not “incorporate a specific and clear mechanism to incorporate new or updated toxicity values,” that new/updated toxicity criteria will require rule amendments and associated regulator and community cost for these amendments, and last, these costs should be provided in the Economic and Fiscal Impact Statement.

Response. The commenter is correct in noting that new and updated toxicity criteria will be incorporated via future rule amendments under the Administrative Procedures Act (APA) as discussed in the comment responses in the Comment Category “Updating the Rule” in Attachment 1. The proposed rule does not include specific language on how new and updated toxicity criteria will be adopted, because it is unnecessary to duplicate existing law and regulations. Accordingly, no changes to the rule are needed in response to the comment.

To further clarify this point, as discussed in the section “Updated/New IRIS Toxicity Criteria” in the FSOR, the rule already allows for a subsequent, more stringent IRIS value to be used in place of a less stringent Appendix I value immediately, and without further rulemaking. DTSC would immediately apply the IRIS value to risk assessments and risk-based calculations, and seek to update the rule to provide timely notice of the change. DTSC could also seek to do an emergency rulemaking to make the change so that Appendix I could remain as current as possible while still reflecting values that meet the statutory standard of HSC §25356.1.5. This would also be true if OEHHA were to develop a better toxicity criteria value that was more protective than the value already in Appendix I.

To the extent that a more scientifically defensible and less stringent value becomes available from either OEHHA or IRIS after a peer review process meeting the requirements of HSC §57004, DTSC would also seek to do a rulemaking to replace an outdated OEHHA value in Appendix I because that outdated value would no longer comply with HSC §25356.1.5. DTSC would seek to do this in the most expedited fashion, possibly an emergency rulemaking. The benefit in reducing the uncertainty and DTSC and responsible party resources devoted to determining what is the appropriate and acceptable toxicity criteria to use for the cleanup of each site far exceeds the limited resources necessary to make future amendments to incorporate toxicity criteria values which have already undergone peer review and adopted by OEHHA or IRIS.

Comment CCEEB-18. The commenter requests that DTSC “maintain its flexibility in determining the best toxicity criteria value...associated with site specific conditions.”

Response. DTSC does not believe that it is necessary to revisit the rule to address this concern because the rule retains DTSC’s existing flexibility in determining toxicity criteria where necessary, while still complying with HSC §25356.1.5 requirements, specifically with respect to values under §69021(c). However, as explained in the comment responses in the Comment Category “Flexibility in Selecting Toxicity Criteria and Setting Site-Specific Remediation Goals,” in Attachment 1, toxicity criteria are specific to the contaminant present at the site, and reflect the characteristics of the contaminant itself rather than the use decisions that may apply to any particular property or “site specific conditions.”

DTSC is also retaining its discretion and “flexibility” when using the toxicity criteria with chemical and site-specific considerations in the risk assessment formulas and analyses conducted in accordance with the NCP, CERCLA, Resource Conservation and Recovery Act, and applicable state and federal guidance. For example, during the risk assessment, if a metal is designated as a contaminant of concern, the toxicologist will ensure that the toxicity criteria is specific to the type or “form” (e.g., alloy or compound) of the metal present at the site as well as the concentrations that exceed background levels. This is appropriate under HSC §25356.1.5 because the toxicity criteria for the metal in Appendix I may not actually reflect the properties of the metallic compound or alloy at issue.

Also, please see specific response to comments SCO-2.

California Manufacturers and Technology Association

Below are responses to comments from California Manufacturers and Technology Association (CMTA). CMTA also provided comments as part of the SCO. SCO comments are addressed later in this Attachment to the FSOR. Finally, CMTA also provided 30 comments on the August Proposed Rule, therefore the comment numbers below begin with CMTA-31.

Comment CMTA-31. The commenter states that the proposed rule is inconsistent with U.S. EPA OSWER Directive 9285.7-53.

Response. DTSC believes that the cited OSWER Directive allows use of high quality state-developed toxicity criteria as being implemented by the proposed rule. As explained in the ISOR, and in the comment responses in the Comment Categories “Best Available Science,” “Rule Not Needed,” “Consistency with Federal/State Laws and Guidance,” and “Financial Considerations,” the proposed rule is explicitly consistent with the OSWER Directive. DTSC also notes that peer-reviewed OEHHA toxicity criteria are among those suitable non-IRIS values that can be used at cleanup sites pursuant to the OSWER Directive. Further explanation on how the proposed rule is consistent with U.S. EPA guidance is provided in the FSOR and in the response to CMTA-39.

Comment CMTA-32. The commenter states that the “proposed regulation focuses on ensuring use of the most stringent toxicity criteria in the risk assessment” and that DTSC is promulgating the rule to “settle a long-running dispute with the U.S. Air Force at a single site” which is a “disproportionate reaction that will negatively impact many sites.”

Response. DTSC believes that stringency is not a consideration; while the primary objective in the selection of toxicity criteria is protection of human health, DTSC is also statutorily obligated to use best available science in compliance with HSC §25356.1.5 and HSC §57004. Furthermore, adoption of the rule is necessary to set clear and consistent statewide health protection standards for all cleanup sites, and does not only apply to the Air Force. This is discussed in DTSC’s responses in the Comment Categories “Best Available Science” and “Rule Not Needed” in Attachment 1.

Comment CMTA-33. The commenter states that the proposed rule does not apply a “science-based approach” but rather simply applies the most stringent toxicity criteria for listed contaminants as shown in the table provided with the comment. The table compares U.S EPA and DTSC inhalation screening levels. Furthermore, “DTSC has not provided evidence supporting the need to use more restrictive toxicity criteria in California relative to USEPA and other states.”

Response. As explained in DTSC’s responses in the Comment Categories “Best Available Science” and “Basis for Toxicity Criteria” in Attachment 1, in selecting the appropriate toxicity criteria for California hazardous waste and substance release cleanup sites, DTSC specifically applies best available science criteria in accordance

with HSC §25356.1.5 and §57004. For contaminants where values are available from both OEHHA and IRIS, but are equivalent in meeting best available science requirements, DTSC in general chooses the more protective value to reflect California-specific expectations and considerations. Toxicity criteria developed by OEHHA are consistent with their guidance documents and requirements under state law such as the California Children’s Environmental Health Protection Act (Senate Bill No. 25, Escutia, chaptered 1999, 1998-99 Reg. Sess.).

The screening levels listed in the commenter’s table do not accurately reflect the toxicity criteria in Appendix I of the rule. Toxicity criteria are only one parameter, and there are several other exposure parameters that are used in the equation to derive the inhalation screening levels. The toxicity criteria for seven of the screening levels (e.g., 1,4-dioxone, chlordane, and carbon tetrachloride) in the commenter’s table are not included in Appendix I; in those cases, DTSC recommends using the IRIS values which though “less stringent” represent the best available science. For more details on how the toxicity criteria in Appendix I were selected, please also see the FSOR.

Comment CMTA-34. The commenter states that there is no need to codify toxicity criteria and DTSC should continue the current practice of applying existing guidance on selecting toxicity criteria. Furthermore, the commenter stated the rule is not needed “in light of DTSC’s acknowledgement in the ISOR that the proposed rule may result in a ‘loss of discretion to choose remediation goals within the risk management range of 10^{-4} and 10^{-6} .’”

Response. DTSC believes that codifying the toxicity criteria, as proposed in this rule, will provide both clarity and consistency, and complies with the state law. Because DTSC intends to apply the Appendix I toxicity criteria statewide, a rule is appropriate under the APA. The reasons for the proposed rule are explained in the ISOR and in the comment responses in the Comment Categories “Best Available Science” and “Rule Not Needed” in Attachment 1. The commenter’s selective and specious use of text from the ISOR implies incorrectly that DTSC stated that the proposed rule will result in a loss of discretion in selecting remediation goals. As stated in the ISOR, some commenters in the public workshop expressed this concern, not DTSC. And in fact, the proposed rule does nothing that will reduce DTSC’s discretion in selecting remedies or setting remediation goals.

Comment CMTA-35. The commenter states that because proposed §69021(a) states that Appendix I values shall be valid as long as they are “no less stringent” than IRIS values, site investigation and remediation costs will increase because the most stringent of OEHHA or IRIS values will be applied.

Response. As described in the ISOR and further explained in the comment responses in the Comment Categories “Basis for Toxicity Criteria,” “Changing Existing Practice,” and “Financial Considerations” in Attachment 1, the rule adopts the same approach of selecting toxicity criteria that has been in effect since at least 1994 and so will not

increase the costs of site investigation and remediation. As discussed in the comment response under the Comment Category “Updating the Rule” in Attachment 1, DTSC will also update the rule as appropriate to adopt new and updated appropriate toxicity criteria.

Comment CMTA-36. The commenter states that the proposed rule lacks a “concrete and transparent administrative mechanism to incorporate new or updated toxicity criteria,” nor a schedule for updating the rule, and “it is not clear...how HERO semiannual updates...will ultimately be incorporated into the regulation.”

Response. DTSC believes that the ISOR and comment response in the Comment Category “Updating the Rule” in Attachment 1 is clear and transparent about how new and updated toxicity criteria will be adopted and approximately how often the rule will be adopted to incorporate these new or updated criteria. DTSC plans to comply with existing rulemaking law, which does not need to be repeated or duplicated in this rule. Furthermore, the referenced “semiannual updates” refer to the forthcoming HERO HHRA Note. The toxicity criteria listed in the forthcoming HHRA Note will be those values already in use in the U.S. EPA regional screening levels and HERO’s HHRA Note 3 and are the only available toxicity criteria for that contaminant.

Comment CMTA-37. The commenter states that: 1) the proposed rule, by requiring future amendments, will impose a significant resource burden on DTSC and associated cost burden on “regulated entities; 2) site investigations and remedial plans will also need to be updated on a more frequent basis; and 3) the annual updates will “ensure that toxicity criteria are as stringent as possible, with no recognition that best available science in the future could indicate less toxicity” for a given contaminant.

Response. Regarding financial impact, DTSC would like to note that the ISOR and DTSC’s responses in the Comment Category “Financial Considerations” in Attachment 1, and the revised Attachment to Form 399 clearly explain that there will be no financial burden on regulated entities, as the annual amendments costs are nominal and will be performed under DTSC’s regulations budget. Furthermore, as explained in the comment responses in the Comment Categories “Best Available Science,” and “Basis for Toxicity Criteria,” the selection of toxicity criteria will be based on best available science, which includes potentially adopting a new or updated less stringent criteria if adequately supported. Given that the APA requires rulemaking for rules of general application such as this, DTSC must comply with the APA unless and until it obtains a statutory exemption from that law. In addition, the benefit in reducing the uncertainty and DTSC and responsible party resources devoted to determining what is the appropriate and acceptable toxicity criteria to use for the cleanup of each site far exceeds the limited resources necessary to make future amendments to incorporate toxicity criteria values which have already undergone peer review and adopted by OEHHA or IRIS.

Comment CMTA-38. The commenter believes that population-specific variations in health endpoints should be specific to the population at the evaluated site, and as an example, OEHHA's more stringent (than IRIS) tetrachloroethylene (PCE) toxicity value should not be applied at sites that have a parking lot or are otherwise "capped" as the population will not be exposed to the PCE vapors.

Response. DTSC does not believe that it is necessary to change the rule based on this comment. The anticipated use of a property is a site-specific parameter that affects the remediation goal and any use restrictions selected as part of the remedy. Such site-specific considerations do not affect the toxicity criteria, which is the inherent potency number for the chemical or contaminant. As explained in the ISOR, and in DTSC's responses in Comment Categories "Best Available Science" and "Site Evaluation" in Attachment 1, toxicity criteria are "contaminant-specific" and do not take into account site-specific considerations. These instead are factored into the risk assessment and remedy evaluation and selection which are conducted pursuant to the Nine Criteria in the NCP. In the example provided by the commenter, to the extent that the cap was demonstrated to reliably prevent exposure to PCE vapors over the long term, then the toxicity criteria would not likely be a factor in the selection of that alternative.

Comment CMTA-39. The commenter states that the proposed rule will eliminate the flexibility for toxicologists and risk managers to use alternative values on a case-by-case basis pursuant to OSWER Directive 9285.7-53.

Response. The proposed rule is consistent with the OSWER directive on the following essential points:

- The referenced OSWER directive presents "current ... technical and policy **recommendations** [emphasis added]."
- "state personnel may use and accept other technically sound approaches..."
- "EPA will, and States should, consider whether the recommendations or interpretations of this memorandum and appropriateness of the application of this document to a particular situation."
- This memorandum does not impose any requirements or obligations on EPA, States..."

Furthermore, the directive uses the term "case by case basis" in the context of a party bringing to EPA's attention additional scientific information (on toxicity criteria) that the EPA should consider in the decision-making process. For example, the response to Comment CCEEB-18 discusses how risk assessors may decide not to use the toxicity criteria for the metallic element, because the form of the metal present at a site differs significantly from the form of the elemental metal studied for the available toxicity criteria. Furthermore, the risk assessment may propose with supporting documentation the use of a value different than that provided in Appendix I and IRIS. DTSC will review the proposal and in concert with OEHHA, pursue appropriate updates to their toxicity criteria, and to the rule.

Because the proposed rule and activities under the proposed rule must comply with HSC §25356.1.5, DTSC cannot preclude consideration of additional, better scientific information on toxicity criteria from being evaluated in future risk assessments. And where that value is a state value that also satisfies §57004 for peer review, it can be added to Appendix I or its lesser-science counterpart can be deleted through an emergency rulemaking.

DTSC agrees that the purpose of the rule is to adopt consistent statewide health protections in accordance with the requirements of HSC §25356.1.5 and §57004, and limit the time spent in disputes over toxicity criteria statewide. For these reasons, it is not necessary to revise the rule.

Comment CMTA-40. The commenter notes that rule amendments to adopt new/updated toxicity criteria is a time-consuming process and will be too late to apply toxicity criteria based on best available science to some cleanup decisions.

Response. DTSC is legally obligated to follow the APA unless and until it obtains a statutory exemption from rulemaking laws. However, DTSC favors the transparency that comes with a public rulemaking process. In comment responses in the Comment Category “Updating the Rule” in Attachment 1, DTSC explains how new/updated toxicity criteria not yet incorporated by rule are used in the decision-making process for sites. Please also refer to DTSC’s responses below to Latham and Watkins (L&W) comments L&W-06.1 and -06.2 regarding updates to Appendix I.

Comment CMTA-41. The commenter states that the proposed rule will force the responsible party to potentially apply outdated toxicity criteria in risk assessments and site environmental decisions. This in turn will result in increased site investigation work and higher cleanup costs which should be identified and evaluated in Department of Finance Economic Impact Standard Form 399.

Response. The response to comments under the Comment Category “Updating the Rule” and General Comment Category “Financial Considerations” in Attachment 1 explain how site decisions will be made based on the most current toxicity criteria and demonstrate that there are no increased costs to responsible parties. Please see also the Response to CMTA-40 above and L&W-06.1 and -06.2 below.

Comment CMTA-42. The commenter states that the proposed rule “locks in Appendix I (OEHHA) values or IRIS values” (depending upon the criteria) which is inconsistent with the flexibility specified in OSWER Directive 9285.7-53.

Response. DTSC acknowledges that the purpose of the rule is to adopt consistent statewide health protections but does not believe that it is necessary to revise the rule language in response to this comment. Please also see the response to CMTA-39 above, as well as CMTA-57 below regarding flexibility inherent in setting the remediation goal and selecting the remedy.

Comment CMTA-43. The commenter states that the value listed in Appendix I Table 2 is a “risk management decision” rather than a “toxicity criteria” as specified in the Appendix. Furthermore, the commenter stated that at a minimum, the term “toxicity criteria” should be defined.

Response. DTSC would like to clarify that the blood lead value listed in Appendix I Table 2 is a toxicity criterion and not a risk management decision. The blood lead value is a child-specific health guidance value based on a benchmark incremental change in blood lead concentrations. DTSC does not believe that the term “toxicity criteria” should be defined in the rule as the U.S. EPA Risk Assessment Guidance for Superfund (RAGS) Part A (https://www.epa.gov/sites/production/files/2015-09/documents/rags_a.pdf) already defines toxicity criteria (values). Therefore, it is not appropriate to remove Table 2 or its value from the proposed rule.

Comment CMTA-44. The commenter states that the following statement in Attachment 1, “Toxicity criteria are not site-specific values and the same toxicity criteria would be selected regardless of the site use/reuse and receptors” contradicts other statements in the RTCs, past and current practice, and OSWER Directive 9285.7-53.

Response. DTSC has crafted the proposed rule to be consistent with existing practice and the cited OSWER Directive, so DTSC does not believe that it is necessary to make revisions to the rule based on this comment. As explained in DTSC’s responses in the Comment Category “Flexibility in Selecting Toxicity Criteria and Setting Site-Specific Remediation Goals” in Attachment 1, toxicity criteria are specific to a contaminant. Site-specific considerations are factored into the risk assessment and toxicity criteria are only one component of the risk assessment. Furthermore, the proposed rule is consistent with past and current practice, and as discussed in the response to comment CMTA-39 above, OSWER Directive 9285.7-53.

Comment CMTA-45. The commenter notes that the proposed rule requires the use of the toxicity values presented in Appendix I, and if not Appendix I then IRIS, even if the form of the metal present at the site is different than the form for which the OEHHA/IRIS toxicity criteria has been established. This could result in applying the wrong toxicity criteria for a metal present at the site.

Response. As explained in the ISOR, the proposed rule “would not require use for metallic or metalloid element COPCs [contaminant of potential concern], (e.g., alloys), that differ in form from the primary compound on which the toxicity criteria are based.” Furthermore, as explained in the comment response in the Comment Category “Flexibility in Selecting Toxicity Criteria and Setting Site-Specific Remediation Goal” in Attachment 1, consistent with historical practice, risk assessors are to consider the form of the metal present at the site when developing the risk assessment and states, “Accordingly, the rule will not change how risk assessments evaluate metals or how risk assessments are used in selecting remediation goals.” Please note that as part of the risk assessment, the toxicologist uses contaminant-specific toxicity criteria as well as

various site-specific factors in determining human health risk (such as the receptors and site use). Please also see the response to CCEEB-18.

Comment CMTA-46. The commenter requests that DTSC “clarify that background contaminant concentrations may include both naturally occurring chemicals and anthropogenic sources.”

Response. DTSC believes that this comment is beyond the proposed rule’s scope. The commenter is referring to a sentence in the comment response in the Comment Category “Flexibility in Selecting Toxicity Criteria and Setting Site-Specific Remediation Goals” in Attachment 1 where DTSC was identifying various site-specific considerations in the risk assessment. Note that as explained in the response to comments under the Comment Category “Background Levels” in Attachment 1, background contaminant concentrations are not relevant to the proposed rule. “Anthropogenic background” concentrations may or may not be factored into the risk assessment depending upon the site-specific circumstances. This issue should be addressed during the individual site-specific risk assessments and not as part of the present rulemaking.

Comment CMTA-47. The commenter reiterates that the proposed rule will result in the “re-opening” of previously closed sites.

Response. As stated in the comment response in the Comment Category “Five-Year Reviews and Changes to Existing Decisions” in Attachment 1, the proposed rule does not trigger re-opening of sites. Please also see the response to L&W-06.6 below regarding Five-Year Reviews.

Comment CMTA-48. The commenter reiterates that the proposed rule will result in the required use of “outdated” toxicity criteria for risk assessments and decision-making purposes.

Response. DTSC refers the commenter to the responses to comment CMTA-40 above and L&W-06.1 and -06.2 below.

Comment CMTA-49. The commenter reiterates that the proposed rule “precludes use of updated values until they are incorporated into the rule by formal rulemaking process.”

Response. DTSC refers the commenter to the responses to CMTA-40 above and L&W-06.1 and -06.2 below. The section “Updated/New Toxicity Criteria” in the FSOR also explains how updated more stringent IRIS values will automatically supersede values in Appendix I.

Comment CMTA-50. The commenter presents excerpts of text in OSWER Directive 9285.7-53 and implies the proposed rule is inconsistent with the directive by quoting the

following from the directive: “flexibility to consider toxicity criteria on a case-by-case basis.”

Response. DTSC refers the commenter to the response to comment CMTA-39 above.

Comment CMTA-51. The commenter references a statement in the comment response in the Comment Category “Flexibility in Selecting Toxicity Criteria and Setting Site-Specific Remediation Goals” in Attachment 1 as evidence that for some sites, the proposed rule will result in an overestimation of site risk and thus increased costs to the responsible party. The bolded text associated with the comment implies that these additional costs to the responsible party must be factored into the CEQA analyses.

Response. The commenter is referring to the following statement in Attachment 1: “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.” Please see the response to comment CMTA-45 above.

Comment CMTA-52. The commenter states that the “proposed regulation requires the selection of the most stringent toxicity criteria” and not “based on best available science” which “will bias the risk management decision toward lower cleanup levels.”

Response. DTSC refers the commenter to the responses to comments 18ECO-01 and -02, and CMTA-32, -33, and -37 above.

Comment CMTA-53. The commenter states that the proposed rule eliminates the use of alternative criteria, which will result in an overestimate of risk for some sites, leading to higher costs which need to be incorporated into the Economic and Fiscal Impact Statement (Form STD399).

Response. DTSC refers the commenter to Attachment 1 and reiterates that the proposed rule reflects present practice in accordance with HSC §25356.1.5. As stated in the comment response in the Comment Category “Economic Impact (Form 399)” in Attachment 1, the proposed rule does not change from existing or historic practice the process for selecting toxicity criteria and as such, the filed Form 399 is correct that there will be no fiscal impact to businesses in California. Please also note, as explained in the response to comments CCEEB-18, CMTA-39, and CMTA-45 above, if appropriate, for certain site-specific situations, alternative criteria may be selected in the risk assessment.

Comment CMTA-54. The commenter states that the proposed rule is inconsistent with OSWER Directive 9285.7-53, mandates the use of specific values for certain contaminants, and allows no flexibility to select alternative values unless those values are later adopted via rule amendment.

Response. DTSC agrees that the proposed rule is adopting certain values for application statewide, but does not believe that the proposed rule is inconsistent with the OSWER Directive. Please see the response to CMTA-39 above. Furthermore, as discussed in the ISOR, consistent with DTSC's statutory obligation under its various laws to protect human health from hazardous waste and substance releases to the environment and as such may mandate the selection of toxicity criteria for human health risk.

Comment CMTA-55. The commenter states that "failure to provide the flexibility to consider alternative criteria...means that the proposed rules conflict with the federal regulations."

Response. DTSC refers the commenter to the responses to comments CCEEB-18, and CMTA-31, -37, -39, -44, and -45.

Comment CMTA-56. By citing certain text in Attachment 1, the commenter states it is "DTSC's intention to make mandatory the criteria specified in the proposed regulation."

Response. DTSC agrees with the commenter and also refers the commenter to the response to comment CMTA-54.

Comment CMTA-57. The commenter states that: 1) the rule does not provide a provision to apply a less stringent IRIS value in the future if it is based on best available science; 2) California will only accept a 1 in 1 million acceptable risk level as the remedial goal for any Superfund site in California; and 3) the difference between the OEHHA and IRIS toxicity criteria for PCE is simply "a difference in scientific opinion."

Response. DTSC agrees that the rule itself does not have language to automatically use more recent IRIS values, because that determination must be made in concert with OEHHA in compliance with HSC §25356.1.5. However, that statute does require use of best available science with consideration of California's sensitive subpopulations, so a future, less stringent IRIS value based on better science could warrant a change to Appendix I. The values in the rule specifically reflect best (presently) available science as required by the statute. For example, more protective OEHHA criteria are not listed for 1,4-dioxane, benzo[a]pyrene and carbon tetrachloride because they did not meet the best available science requirement. Should a less-stringent IRIS value be issued based on better science in the future, DTSC will evaluate the derivation of the value and determine if the corresponding Appendix I value should be removed from the rule consistent with HSC §25356.1.5 and §57004.

The commenter's statement that DTSC specifies remedial goals only at 1×10^{-6} is incorrect. DTSC is required by state law to comply with the NCP with respect to the point of departure and the risk range. In fact, the target risk is one of the inputs required in the equation used to determine remedial goals. The target risk is a site-specific risk

management decision and can be any value within the risk range. Therefore, this comment is beyond the scope of the regulation. Nevertheless, in order to address this misunderstanding, DTSC will provide further guidance and outreach that will confirm that the rule neither defines remediation goals as screening levels, nor prohibits them from being set at the same level; and that DTSC will continue to utilize the risk range in risk-management decisions.

Finally, DTSC disagrees with the statement that the difference between the IRIS and OEHHA toxicity criteria value for PCE is simply a difference in scientific opinion. For details, please see the comment response in the Comment Categories “Best Available Science” and “Derivation of Toxicity Criteria” in Attachment 1.

Also please see specific responses to comments CCEEB-16, COC-07, L&W-06.4 and SCO-2.

CMTA-58. The commenter states that “OEHHA toxicity values have not historically been subject to the same level of external scientific peer review and public input as values developed under the EPA IRIS program.”

Response. This comment pertains to development of the OEHHA values rather than the language of the proposed rule. As discussed in the comment response in the Comment Categories “Basis for Toxicity Criteria” and “Best Available Science” in Attachment 1, the toxicity values listed in Appendix I have undergone rigorous scientific assessment and peer review in accordance with best available science practices in HSC §25356.1.5 and §57004, and are deemed on par with toxicity criteria provided in the IRIS database. As mentioned earlier, any toxicity criteria value that had not undergone this rigorous peer review has been removed from Appendix I of the proposed rule.

Comment CMTA-59. The commenter requests clarification as to why DTSC claims that the 2017 U.S. EPA IRIS oral cancer slope factor (CSFo) for benzo[a]pyrene (B[a]P) is based on best available science yet recommends the use of the 1994 OEHHA inhalation unit risk (IUR) factor. The commenter recommends that “DTSC update HERO Note 3 to show the inhalation URF [unit risk factor] for these PAH [benzo[a]anthracene, benzo[b]fluoranthene, benzo[k]fluoranthene, chrysene, and indeno[123cd]pyrene scaled from the B[a]P IRIS (2017) URF of 0.0006 per microgram per cubic meter.” The commenter states the source for the CSFo for dibenzo[a,h]anthracene is not defined in Appendix I or the regulatory text and that the IUR listed in Appendix I does not reflect the value listed in the provided supporting documentation. Additionally, the commenter notes that DTSC included as part of the supporting material the 1992 OEHHA “Expedited Cancer Potency Values and Proposed Regulatory Levels for Certain Proposition 65 Carcinogens” and that the development of the toxicity criteria “was an “early short cut” to get Proposition 65 potency values” and that they no longer meet the criteria for rigorous external peer review and best science.

Response. DTSC recommends using the 2017 IRIS CSFo for benzo(a)pyrene not only because it represents best available science, but also because the OEHHA CSFo value

from the 2010 public health goal did not go through a peer review and thus does not comply with HSC §57004. Regarding updates to the HERO HHRA Note 3, once the rule is final and effective, HHRA Note 3 will be updated accordingly. However, DTSC disagrees with using the 2017 IRIS IUR for B[a]P, will continue to recommend the OEHHA IUR, and believes that it is not appropriate to be scaling the IUR for the chemicals mentioned in the comment.

The commenter is correct that “OEHHA ECP” was not defined in Appendix I or the regulatory text. Appendix I has been modified so that the source is cited as “OEHHA” rather than “OEHHA ECP;” this change is appropriate as DTSC relies on the toxicological expertise of OEHHA, and after collaboration with OEHHA, OHHEA staff confirmed that those toxicity criteria have undergone peer review and acceptance after the Expedited Cancer Potency (ECP) process initially used by the Proposition 65 Program. The commenter is also correct that the supporting material provided as a curtesy titled “6. Polynuclear Aromatic Hydrocarbons” does not discuss the dibenzo[a,h]anthracene IUR listed in Appendix I. DTSC points the reader to page 91 of Number 5 on the DTSC website under the “Supporting Documents for Analytes Listed in Appendix I of the Proposed Regulation.” This technical document is available online at: <http://dtsc.ca.gov/LawsRegsPolicies/Regs/upload/5-Benzidine-Bis-2-Chloroethyl-ether.pdf>.

The toxicity criteria (CSFo and IUR) listed in Appendix I were submitted to the OEHHA Air Toxics Hot Spots Program as a Technical Support Document which listed and described the derivation of cancer potencies for the individual contaminants. The Technical Support Document was peer reviewed by the Scientific Review Panel and was made available to the public for review and comments. DTSC collaborated with OEHHA, and OEHHA staff confirmed that these values meet HSC §25356.1.5 and §57004. For further details on this, please see the response to 18ECO-02 and Supplement 1 to this response to comments.

Comment CMTA-60. The commenter states that: 1) the U.S. EPA IRIS PCE toxicity criteria was developed to protect all populations, represents best available science, and went through an extensive internal/external peer and public review; 2) U.S. EPA IRIS PCE cancer potency estimates remain protective; and 3) that the Spearow et al. (2017) paper should be subject to independent critical review that address the issues identified in the commenter’s analysis.

Response. DTSC believes that the OEHHA PCE IUR represents best available science and that the IRIS PCE IUR is not appropriate for use in California as previously discussed in the comment responses in the Comment Categories “DTSC Tetrachloroethylene (PCE) Published Paper” and “Attachment 1: Detailed Response to Comments on the Spearow et al. Paper” in the RTCs to the August Proposed Rule. The Spearow et al. (2017) paper was subject to independent peer review per the guidelines of the journal by which it was accepted and published. DTSC believes its synthesis and analysis of the studies, as presented, is compelling science that demonstrates the appropriateness of the OEHHA PCE IUR.

Comment CMTA-61. The commenter questions DTSC’s decision to reject the U.S. EPA IRIS IUR value for 1,3-butadiene, which is based on an epidemiological study, while recommending the OEHHA benzene toxicity criteria, which is also based on an epidemiological study. The commenter requests that DTSC provide its rationale for the chemical-specific reviews of the “best available science” base for each chemical.

Response. DTSC believes the OEHHA toxicity criteria listed in Appendix I represents best available science. DTSC does not oppose using epidemiological data to derive toxicity criteria. Epidemiological data with high confidence may be superior to modeling animal data. However, the response in the Comment Category “Basis for Toxicity Criteria” in Attachment 1, provides a detailed explanation why DTSC, in coordination with OEHHA, rejected the U.S. EPA IRIS IUR value for 1,3 -butadiene. Note that for contaminants where peer-reviewed values are available from both OEHHA and IRIS, DTSC in general chooses the more stringent value to reflect California-specific considerations of protectiveness provided that the OEHHA value represents best available science and was peer reviewed in accordance with HSC §25356.1.5 and §57004.

City of Compton

DTSC received the City of Compton (COC) comments on May 30, 2018, 39 days after closure of the comment period. However, in the interest of addressing all input received without delaying the rule, DTSC provides the following responses.

Comment COC-01. The commenter states that the proposed rule will result in a loss of flexibility for toxicologists to consider site-specific factors in selecting toxicity criteria.

Response. Please see the response to Comment CCEEB-18 above which directly addresses this comment.

Comment COC-02. The commenter states that the rule will “likely slow or derail voluntary actions to redevelop Brownfields” because the rule does not allow risk managers to consider new studies demonstrating lower toxicity for a given contaminant at a site.

Response: DTSC believes the rule will not slow down or derail cleanup actions as the rule simplifies the selection of toxicity criteria and requires use of the best available toxicity criteria that meet the statutory requirements of HSC §25356.1.5. Further explanation of the simplified selection is in the responses to Comments CMTA-35, -41, and 45 above, and of the use of new appropriate toxicity criteria is in the responses to Comments CCEEB-17 above and L&W-06.1 and -06.2 below.

Comment COC-03. The commenter states that the rule is inconsistent with DTSC guidance which “...provides for the review of toxicity value applicability on a site-by-site basis.”

Response. Although not specific on which DTSC guidance the rule appears to conflict with, the commenter references HERO Note 5. DTSC does not believe the rule conflicts with DTSC guidance. In particular, as discussed in the response to Comments CCEEB-18, and CMTA-44, -45 and -46 above, site-specific considerations are considered and used with the toxicity criteria in the risk assessment.

Comment COC-04. The commenter states that cleanups will be more complex, time consuming and more expensive.

Response. DTSC believes instead that the rule will result in less complex and time-consuming, and potentially less expensive, cleanup actions because the rule simplifies the selection of toxicity criteria and likely will lead to less time spent on fewer disagreements and disputes regarding which toxicity criteria to use at hazardous substance release cleanup sites in California. For details, please see the responses to Comments CMTA-35, -41, and -51 above. Also, as described in the ISOR and further explained in the Comment Categories “Basis for Toxicity Criteria,” “Changing Existing Practice,” and “Financial Considerations” in Attachment 1, the rule adopts the same approach of selecting toxicity criteria that has been in effect since at least 1994, and as such, will not increase the costs of site investigation and remediation.

Comment COC-05. The commenter believes that the rule is being implemented primarily to resolve a dispute with the Air Force on the appropriate toxicity criteria for PCE; and this does not warrant “suspending scientific discretion at all sites.”

Response. While the referenced dispute was the first time that differing interpretations of federal guidance on toxicity criteria required formal resolution, the referenced dispute was neither the “primary” nor sole reason for the rule. DTSC explains the reasons for the rule in the Executive Summary in Attachment 1. DTSC explains the benefits of the rule in the *45-Day Public Notice and Comment Period*, and the private sector cost benefits of the rule in the Attachment to Form 399 in the rule package. Furthermore, DTSC does not agree that the rule suspends “scientific discretion” in evaluating hazardous substance release cleanup sites. The rule, as proposed, complies with federal guidance and practice and with HSC §25356.1.5. Regarding the term “scientific discretion”, DTSC assumes the commenter is referring to the taking into consideration site-specific factors into the risk assessment which is addressed in the response to Comment COC-01 above.

Comment COC-06. The commenter requests the following “amendment” to the rule: “Restore discretion to DTSC to consider values other than the OEHHA Appendix 1 values.”

Response. In slightly different words, this request is virtually the same as Comment SCO-01 below, and is addressed in our response to that comment.

Comment COC-07. The commenter requests the following “amendment” to the rule: “Clarify that the NCP risk range applies during remedy selection.”

Response. In slightly different words, this request is virtually the same as Comments CCEEB-16, CMTA-57, L&W-06.4 and SCO-02, and is addressed in our response to these comments.

Comment COC-08. The commenter requests the following “amendment” to the rule: “Eliminate OEHHA values for BaP and values for compounds derived from BaP, based on DTSCs admission that the 2017 IRIS values represent the best available science.”

Response. In slightly different words, this request is virtually the same as Comment SCO-03 below, and is addressed in our response to that comment.

Committee to Bridge the Gap

Below are responses to comments from Committee to Bridge the Gap (CBG). CBG submitted nine comments on the April proposed rule, therefore the comment numbers below begin with CBG-10.

Comment CBG-10. The commenter notes that in December 2016, DTSC convened a “pre-rulemaking workshop” and stated that it was “entirely, or almost entirely attended by lobbyists and other representatives of parties that have an interest in assuring that standards were as weak as possible.” The commenter implies that DTSC “weakened” the rule to accommodate special interests and states that DTSC was proposing to use the “least protective standard” for toxicity criteria in the proposed rule.

Response. DTSC did not “weaken” the proposed rule, but revised the rule to align with governing statutes HSC §25356.1.5 and §57004. For more details please see the response to CBG-11 below.

During the first (45-day public) comment period, CBG submitted comments on the August Proposed Rule, including a comparison of various toxicity criteria from OEHHA and IRIS that appears to be based on a misunderstanding of which toxicity criteria are more stringent. Because the CSFo values represent the slope of a line, a higher value is the more stringent value. In DTSC’s responses in the Comment Category “Requested Revisions to Appendix I” in Attachment 1, DTSC explained the errors in the commenter’s analysis. Contrary to the CBG’s claim, the most protective of scientifically equivalent (based on best available science) OEHHA and IRIS values is being adopted in the proposed rule. This is further explained in the comment responses in the Comment Category “Best Available Science” and “Derivation of Toxicity Criteria” in Attachment 1.

Comment CBG-11. The commenter states that “DTSC should disclose whether additional pressure from industry lobbyists resulted in further weakening of the proposal.”

The commenter includes a timeline of communications with DTSC which the commenter infers show that DTSC “weakened” the proposal in response to industry pressure.

Response. A number of stakeholders, industry representatives among them, have provided input on the proposed rule. Input from CBG and all other commenters has been duly and thoroughly considered. Any resulting modifications to the rule were made to ensure consistency with HSC §25356.1.5 and 57004 while still fulfilling the rule’s intent to provide broad uniform protection of public health and the environment. As explained in the ISOR, the “pre-Administrative Procedures Act” (pre-APA) proposed rule emphasized protectiveness as the most important criterion in selecting appropriate toxicity criteria. While developing the August Proposed Rule DTSC concluded that the rule must also conform to HSC §25356.1.5 and §57004, which specify best available science as the overarching criterion for selecting toxicity criteria. After issuing the August Proposed Rule and April Proposed Rule, DTSC further identified a limited number of criteria in Appendix I that did not meet the best available science requirement and, accordingly, these were removed from Appendix I. See the FSOR and Updated Informative Digest for a more comprehensive explanation for the removal of select criteria from Appendix I.

Upon request, DTSC met with CCEEB, CMTA and SCO. DTSC listened to concerns and answered questions regarding the proposed rule with the CCEEB membership on September 8, 2017, and on May 9, 2018, the CMTA on December 8, 2017, and the SCO on May 9, 2018. DTSC did not make any changes to the proposed rule as a result of these meetings, which were not public workshops or hearings under the APA. DTSC is always interested in all stakeholder concerns and if requested will engage with any stakeholder to explain the rule and likewise answer questions and listen to concerns.

Comment CBG-12. The commenter opposes the changes from the “pre-APA” version of the August Proposed Rule and states that the rule should apply the most protective toxicity criteria for each contaminant.

Response. Toxicity criteria must meet certain legal thresholds to be selected for use in developing health risk assessments, screening levels and remediation goals. As discussed in the responses to comments 18ECO-01 and -02, DTSC is legally required to apply best available science practices in selecting toxicity criteria and thus, for some contaminants, the most protective value issued by OEHHA and IRIS does not meet these statutory criteria.

Comment CBG-13. The commenter states that the rule provides DTSC with authority to “ignore OEHHA standards at will, choosing whenever s/he wishes to use the less protective standard” which “would usurp OEHHA’s fundamental role.”

Response. DTSC notes that it is still bound to comply with applicable law, including but not limited to HSC §25356.1.5 and §57004, and the proposed rule does not expand DTSC’s authority. As discussed in the response to comment 18ECO-02 above, OEHHA is responsible for developing toxicity criteria, while DTSC is responsible for determining

the appropriate toxicity criteria for use at hazardous waste and substance release sites in California. DTSC closely collaborated with OEHHA in the selection of toxicity criteria and the development of this rule; nothing in the proposed rule permits a DTSC toxicologist to ignore OEHHA standards. Further elaboration on the selection of the toxicity criteria in Appendix I is provided in the FSOR and the response to 18ECO-02 above.

Comment CBG-14. The commenter states that “It is up to OEHHA, not DTSC, to determine what values are scientifically supported,” and the proposed rule will “default to more recent, non-protective Trump EPA standards over more protective California standards.”

Response. DTSC values and regularly seeks OEHHA’s expertise, and in fact consulted OEHHA during this rulemaking as noted in DTSC’s response to comment CBG-13. Additionally, in contrast to the commenter’s assertion, the proposed rule does not “default to more recent, non-protective” U.S. EPA values but instead applies best available science principals as discussed in the ISOR, and in the responses to comments in the Comment Category “Best Available Science” in Attachment 1. For example, while the IRIS IUR toxicity criteria value for benzo[a]pyrene is more recent than the corresponding OEHHA value, the “older” but more protective OEHHA criteria is specified in the proposed rule because it satisfies the best available science provisions of HSC §25356.1.5 and §57004.

Comment CBG-15. The commenter states that the proposed rule is opaque and DTSC provides no specific basis or supporting evidence for why particular OEHHA values are included or excluded from Appendix I.

Response. DTSC does not believe that this is the case. In Supplement 1, DTSC has provided information regarding the process for selecting and confirming values for inclusion. As discussed in DTSC’s responses in the Comment Categories “Best Available Science” and “Basis for Toxicity Criteria,” in Attachment 1, DTSC explained the process for selecting toxicity criteria for Appendix I. If values are not listed in Appendix I, then IRIS values should be used. Further details on the process are included in the FSOR and explained in the response to comment 18ECO-02 above, which discusses Supplement 1 that provides information on how DTSC worked with OEHHA to identify toxicity criteria in Appendix I.

Comment CGB-16. The commenter states that because of industry pressure, the term “anticipated land use” was added to the proposed rule which “appears to be an effort by some within DTSC to undermine the position DTSC and CalEPA leadership have taken.” The commenter identified “reasonably foreseeable future land use” as the correct term, and provided additional example factors used in the development of remedial action plans from HSC §25356.1(d)(4).

Response. The term used in the April Proposed Rule is “reasonably anticipated future land uses” which is consistent with longstanding U.S. EPA guidance. Please note, as

explained in the response to comment 18ECO-03 above, land use has no bearing on the selection and use of toxicity criteria, which are the focus of the proposed rule.

Regarding additional site-specific factors in the remediation goal definition, DTSC notes that HSC §25356.1 (which the commenter discusses) pertains to remedial action plans that include implementation considerations under Chapter 6.8, and does not specifically govern the remediation goal itself.

Fresh Air Vallejo

While received separately, Fresh Air Vallejo (FAV) comments are essentially the same as those from “18 Environmental Coalitions and Organizations.” Accordingly, FAV comments are addressed by the responses to the comments from “18 Environmental Coalitions and Organizations” above.

U.S. Department of Defense

Below are responses to comments received from U.S. Department of the Navy for the Department of Defense (DOD). DOD submitted 19 comments on the August Proposed Rule, therefore the comment numbers below begin with DOD-20.

Comment DOD-20. The commenter states that the proposed rule requires use of the most stringent toxicity criteria for a given constituent, rather than the value that uses the most current sound scientific methods, knowledge, and practices of public health and environmental professionals, and therefore the proposed rule conflicts with HSC §25356.1.5.

Response. As noted in DTSC’s response to CCEEB-17, and others, for some contaminants where the most stringent toxicity criteria have not undergone peer review, a less stringent toxicity criteria would apply under the proposed rule. As discussed in DTSC’s responses in the Comment Category “Best Available Science” in Attachment 1, the selection of toxicity criteria is based on best available science practices specifically in accordance with HSC §25356.1.5 and §57004.

Fort Ord Environmental Justice Network

While received separately, Fort Ord Environmental Justice Network (FOEJN) comments are essentially the same as those from “18 Environmental Coalitions and Organizations.” Accordingly, FOEJN comments are addressed by the responses to the comments from “18 Environmental Coalitions and Organizations” above.

Latham & Watkins, LLP

Below are responses to comments from Latham & Watkins, LLP (L&W). L&W submitted five comments on the August Proposed Rule, therefore the comment numbers below begin with L&W-06.

Comment LW-06. The commenter reiterates its comments on the August Proposed Rule suggesting that their comments had not been adequately addressed with respect to the cited legal opinions. The commenter asserts that DTSC’s [preliminary] response to comments (distributed on April 6, 2018) failed to adequately respond to their comments LW-02 and LW-03 in that DTSC did not explain the change made “to accommodate **each objection or recommendation**, or the reasons for making no change [emphasis in original].” Based on a review of the commenter’s September 20, 2017 (“2017 Letter”) and April 21, 2018 (“2018 Letter”) letters, DTSC has identified the following statements that indicate a request for a change to the rule:

L&W-06.1. The commenter states that DTSC must specify the principles that the Supervising Toxicologist must follow in altering the values in Appendix I. (See 2017 Letter, 1st page, 2nd paragraph, 2nd sentence, and 2018 Letter, page 2, 2nd paragraph, 1st sentence.)

L&W-06.2. The Commenter states that DTSC must specify how and why the Appendix can be altered, and whether the public has a right to review and comment on any changes. (See 2017 Letter, 1st page, 2nd paragraph, 3rd sentence, and 2018 Letter, 2nd page, 2nd paragraph, 1st and penultimate sentence.)

L&W-06.3. The commenter states that DTSC must specify the principles that the Supervising Toxicologist must follow in selecting a toxicity criteria under 69021(c). (See 2017 Letter, 1st page, 2nd paragraph, 2nd sentence, and 2018 Letter, page 2, 1st indented paragraph, 1st sentence.)

L&W-06.4. The commenter states that DTSC must address “L&W-02’s objection to the use of a Peer-Reviewed Provisional Appendix Screening Toxicity Value as a cleanup goal.” (See 2018 Letter, 2nd page, last paragraph, 1st sentence; re-characterizing 2017 Letter, 2^{dn} page, 3rd paragraph, 3rd and 4th sentences.)

L&W-06.5. The Commenter requests that DTSC must state that the rule does not apply to sites where a remedy decision document has already been issued. (See 2017 Letter, 2nd page, 1st paragraph, last sentence.)

L&W-06.6. The Commenter requests that DTSC preclude the rule’s application as a newly promulgated ARAR in the Five-Year Review process. The commenter is concerned that this rule will apply the Appendix I values to re-open existing decision documents to revise cleanup levels down to be more protective. (See 2018 Letter, page 2, 2nd paragraph, last sentence.)

Response. DTSC first notes that the draft RTCs provided on April 6, 2018 were preliminary and appreciates the opportunity to expand on its response more fully. DTSC provides additional responses to these comments, as further explained below.

L&W-06.1 and -06.2 – Basis for Altering or Updating Appendix I: Appendix I is expected to be amended in the future because scientific discoveries and studies are always underway that could result in better science or more refined toxicity criteria. The purpose of an amendment would be to update the Appendix to reflect toxicity criteria that meet applicable legal and best available science standards in HSC

§25356.1.5 and §57004; to maintain compliance with the legislative directives in HSC §25356.1.5; and to provide notice to the public of applicable toxicity criteria.

L&W-06.1 and -06.2 –Updating Appendix I (what toxicity criteria values qualify). With respect to the question of what future values might replace existing toxicity criteria values in Appendix I, please note that the analysis of any new (chronic) values must address two prongs – the best available science and the peer review quality. Through addition of the “no less stringent than” language in 69021(a) and the “is more stringent than” language in 69021(b), the proposed rule already allows immediate use of a more recent IRIS value that is more stringent than toxicity criteria value listed in Appendix I to avoid violating the legal requirement in HSC §25356.1.5 for any response action under Chapter 6.8 to be no less stringent than federal NCP, as it may be amended, per HSC §25356.1.5(a).

If a new OEHHA value is issued that constitutes better science and meets the HSC §57004 peer review requirements, DTSC will be aware of that value’s development through its regular contacts with OEHHA, will evaluate the OEHHA technical documents, will confer with OEHHA, as well as begin preparation of any appropriate rulemaking documents. Assuming the new value is better science, the newer value would be the required value under §25356.1.5, and updating the value in Appendix I would be necessary to comply with that statute. In addition, the comment response under Comment Category “Updating the Rule” in Attachment 1, explains how new/updated toxicity criteria are factored into the risk assessment pending a rule amendment. Also, if necessary, DTSC may institute an “emergency rulemaking” to more quickly update Appendix I.

If IRIS issues a fully peer-reviewed value that is less stringent than an Appendix I value, DTSC would similarly be aware of that development, and would confer with OEHHA to determine whether the Appendix I value should be updated by rulemaking. To the extent that a newer IRIS toxicity criteria value is less stringent than an Appendix I value but is more scientifically sound to apply to California’s diverse population and scarce natural resources, DTSC would pursue rulemaking to speed the rule’s compliance with the best available science requirement in HSC §25356.1.5.

L&W-06.1 and -06.2 – Updating Appendix I (how or process). On the process to modify Appendix I of this rule, DTSC does not have a statutory exemption from the APA, and therefore must comply with it. Restatement of the APA requirements in this rule would be unnecessarily duplicative, and would also violate the nonduplication standard applied to regulations under that existing rulemaking law, so it is not appropriated for DTSC to include language in the rule for such rulemaking or rule-changing provisions.

If appropriate, regardless of whether the new value is more or less stringent than its predecessor, DTSC may be able to pursue emergency rulemaking to enable use of the new value sooner than would be possible through the regular non-emergency rulemaking process. As noted above, the update would be necessary to maintain the rule’s compliance with the HSC §25356.1.5 best available science requirements.

Given the limited basis for updating the Appendix I values, updates should become routine and easier for DTSC to process over time.

L&W-06.1 and -06.2 – Updating Appendix I (frequency). In terms of the frequency of updates, DTSC has no reason to anticipate a flood of new, suitable toxicity criteria values to be issued multiple times in a year, and thus does not anticipate a large number of emergency actions. Without knowing for sure what values will finish their peer review processes to become final, DTSC has estimated that it will tentatively update the rule annually, and will likely combine updates as much as reasonably feasible.

L&W-06.1 and -06.2 – Updating Appendix I (public comment). In terms of the public's chance to weigh in on values under consideration for use at cleanup sites, DTSC has identified at least the following four (4) opportunities for public participation and comment:

- Toxicity criteria development – OEHHA and IRIS both use public comment processes to peer review their proposed toxicity criteria. OEHHA's website has a place to sign up for news from them at <https://oehha.ca.gov/about/listserv>. The California Air Resources Board's Scientific Review Panel (SRP) has an e-mail sign up for the public to receive notices of meeting agendas that would include discussion of toxicity criteria under consideration (<https://ww2.arb.ca.gov/news>) IRIS has the same feature (<https://www.epa.gov/iris/forms/staying-connected-integrated-risk-information-system#connect>).
- Workshop(s) -- DTSC will hold at least one workshop when considering addition of pending or newly issued toxicity criteria consistent with HSC §57003.
- Public process under the APA for rulemaking to adopt revised toxicity criteria in Appendix I.
- Public Comment on Cleanup (i.e., Corrective Action and Remedial Decisions) – Remedial decisions are available for public comment under HSC §25358.7, and Corrective Action remedy decisions are publicly noticed in the same fashion.

In addition, where no toxicity criteria have been established in Appendix I (of the rule) or in IRIS, responsible parties have another opportunity to contribute to toxicity value selection under §69021(c) for their own cleanup sites when they propose the toxicity value for use in the risk assessment. The public can still comment on the toxicity criteria used when the remedial decision document becomes available for public comment.

L&W-06.3 – 69021(c) value selection. DTSC disagrees that §69021(c) fails to provide “any intelligible principle that the Supervising Toxicologist must follow in altering the values in Appendix I” because that section explicitly requires that “Any selected toxicity criteria or value used under this subdivision shall be consistent with H SC §25356.1.5, subdivisions (b) and (c).” In fact, this proposed rule is meant to

clarify two specific aspects of HSC §25356.1.5: 1) those toxicity criteria that must be used; and 2) the protection that must be achieved in human health risk-based cleanups. The statutory subdivisions within HSC §25356.1.5 explicitly require that risk assessments be based upon the NCP; U.S. EPA's policies, guidelines, and practices, developed pursuant to CERCLA; 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 ...”

DTSC has referred to these provisions collectively as “best available science” throughout this rulemaking.

Given the clear instruction from the legislature in this regard, and that DTSC cannot implement this rule in excess of its statutory authority, DTSC believes it is unnecessary to revise the rule to duplicate the statutory requirements or constraints in the regulatory text as recommended by the commenter. Furthermore, because HSC §25356.1.5 also requires compliance with federal regulations and guidance, incorporating non-duplicative principles into this rule would risk inadvertent conflict with those federal rules and guidance documents. Full explication of all pertinent statutory regulatory provisions is neither desirable nor required under the nonduplication standard for review of regulations under APA (Gov. Code. 11349(f)).

L&W-06.4 – 69021(c) Toxicity criteria, including a “Peer-Reviewed Provisional Toxicity Values Appendix Screening Toxicity Value,” are inputs for developing cleanup goals and are not cleanup goals in and of themselves. The commenter asserts that the proposed rule could allow “use of a Peer-Reviewed Provisional Appendix Screening Toxicity Value as a cleanup goal.” However, as explained in the comment response under the Comment Categories “Changing Existing Practice, and “Flexibility in Selecting Toxicity Criteria and Setting Site-Specific Remediation Goals” in Attachment 1, toxicity criteria are not cleanup levels (remediation goals). Toxicity criteria are potency factors representing the inherent hazardousness of the chemical without regard to exposure or other site-specific parameters. The toxicity criteria are merely one factor in the risk calculation formula with several other site-specific parameters, including the risk level, whether that is 1 in 10,000 or 1 in a million. Again, the toxicity criteria are not final remediation or cleanup goals, so the rule does not need correction or revision to avoid requiring use of the toxicity criteria as remediation goals. Nevertheless, to further clarify this, DTSC will provide additional guidance and outreach which will specify that DTSC will continue to use the risk range in risk-management decisions.

If a toxicity criterion from the Provisional Peer-Reviewed Toxicity Values (PPRTV) Appendix Screening Toxicity Values source is recommended for use, it is because it is the only toxicity criteria available. The toxicity criteria may be chronic or subchronic

values, and existing federal risk assessment guidance favors use of chronic values for remediation goal setting. The PPRTV Appendix Screening Toxicity Value do receive the same level of internal and external scientific peer review as the PPRTV toxicity criteria, but have more uncertainty which should be considered during the risk assessment process for each individual site. However, the proposed rule does not prevent use of these PPRTV Appendix Screening Toxicity Values. Accordingly, DTSC believes that it is not necessary to further revise the rule to reject the notion that toxicity criteria or PPRTVs are cleanup standards in this rule.

Also, please see specific responses to comments CCEEB-16, CMTA-57, COC-07, and SCO-2.

L&W-06.5 – “Application to established cleanups”. DTSC notes that the rule in §69020(b) expressly “applies to human health risk assessments, human health risk-based screening levels, and human health risk-based remediation goals statewide, where those levels are memorialized in documents approved after the effective date of the rule.” The proposed rule includes no terms to make it retroactive or to apply this rule to remedy decisions predating the rule’s effective date. This rule also incorporates primarily OEHHA chronic toxicity criteria that DTSC has already been using and tracking as DTSC’s running list of toxicity criteria provided in Supplement 1. To the extent that DTSC discovered and updated the list, those few updates are reflected by the inclusion or deletion of a value in Appendix I. Therefore, DTSC believes that it is not necessary to revise the rule as requested to rule out its use at sites with Records of Decision or other remedial decision documents, because the rule already does not reach those documents with effective dates predating the rule.

L&W-06.6 – “Five-Year Reviews”. Where a remedy decision has left waste in place at levels that are not appropriate for unrestricted use and unlimited exposure, CERCLA requires Five-Year Reviews (FYRs) to verify that the remedy is still functioning as intended and is still protective; this is the very purpose of those FYRs. Corrective Action sites may also have FYRs to assure the remedy’s continued protectiveness. Part of the FYR protectiveness determination is a review of the risk assessment parameters forming the basis for the remedy decision and identification of new ARARs and toxicity criteria that might change the lead agency’s evaluation of the remedy’s effectiveness. (See U.S. EPA’s 2003 Fact Sheet: *Five Year Review Process in the Superfund Program*, pp. 4-5.)

Because CERCLA, and its associated risk assessment rules and guidance, as well as DTSC’s various cleanup authorities all share the same goal and requirement of protecting human health, and the values have been in use for DTSC-lead sites, DTSC anticipates no changes in the process for FYR protectiveness determinations on DTSC-lead sites. In addition, DTSC has collaborated with U.S. EPA Region IX such that Region IX has often been using the same toxicity criteria as DTSC at EPA-lead sites in California, so those sites are also unlikely to require changes to their remedies based on adoption of the Appendix I values.

Physicians for Social Responsibility-Los Angeles

Below are responses to comments from Physicians for Social Responsibility-Los Angeles (PSRLA).

Comment PSRLA-01. The commenter asserts that the proposed rulemaking disregards community health and with the rule DTSC is prioritizing polluters' interest before the health and well-being of the people.

Response. DTSC respectfully disagrees and notes that DTSC is committed to execute its mission to protect California's people and environment from harmful effects of toxic substances by restoring contaminated resources, enforcing hazardous waste laws, reducing hazardous waste generation, and encouraging the manufacture of chemically safer products. This includes considering and, where appropriate and possible, addressing concerns raised regardless of who raises the concerns.

As part of the rulemaking, DTSC solicited input by interested parties by issuing publicly noticed a draft "pre-APA" regulatory concept and conducted a workshop on December 12, 2016 in Sacramento to answer questions and solicit input on the proposal. To ensure clarity, and consistency with federal regulations and guidance, and with California statutes, regulations and guidance, and to incorporate public input, DTSC made substantial changes to the regulatory concept, and on August 4, 2017 issued the publicly noticed proposed rule for public comment. DTSC then held two workshops in Northern and Southern California (on August 28, 2017 in Sacramento and August 30, 2017 in Cypress) to answer additional questions and solicit input by interested parties. On September 20, 2017 DTSC conducted a formal hearing in Sacramento to solicit formal comments on the proposed rule. Based on comments received and where appropriate, DTSC made limited, but substantive changes to the proposed rule and issued draft responses to comments and a revised proposed rule with public notice and web postings on April 6, 2018. To further enhance clarity, DTSC has since made a few minor editorial changes and has now issued the Proposed Final Rule to the Office of Administrative Law for review.

DTSC believes the proposed rule is health protective as mandated by California law and addresses all community concerns, as appropriate under DTSC authorities.

Comment PSRLA-02. The commenter states that DTSC "rejected the most protective toxicity criteria" from OEHHA and has "weakened the rule."

Response. Please note that the revisions made to the "pre-APA" version of the August Proposed Rule were to satisfy legal requirements. As discussed in the response to comments 18ECO-01 and -02, and CCEEB-13 above, toxicity criteria are (and must be) selected based on best available science in accordance with HSC §25356.1.5 and §57004. Much as DTSC understands the commenter's concerns, simply because a value is most stringent does not automatically qualify its mandatory use in risk assessments for hazardous waste and substance release sites, if it doesn't constitute best science as required by state law.

Comment PSRLA-03. The commenter objects to “anticipated land use as a criteria [sic] for determining protective standards.”

Response. The intent of the rule is for the selection of toxicity criteria for human health risk assessments, risk-based screening levels, and risk-based remediation goals. While DTSC is required to consider the “reasonably anticipated future land uses” when establishing remediation goals for a site, this rule does not address that. Please see the responses to comments 18ECO-03 and CBG-16 for the reason the term “reasonably anticipated future land use” is included in the definition of remediation goals in the proposed rule.

Comment PSRLA-04. The commenter “urges” that DTSC “require the most protective standard.”

Response. DTSC is required to use toxicity criteria that are based on best available science as specified in HSC §25356.1.5 and may not use toxicity criteria that do not meet those standards, regardless of stringency.

Mr. Michael Rincon

Below are responses to comments from Mr. Michael Rincon (RIN).

Comment RIN-01. The commenter points to an apparent contradiction in DTSC’s responses to comments provided in Attachment 1. On page 21, DTSC states that certain more protective OEHHA toxicity criteria could not be included in Appendix I because they did not comply with HSC §25356.1.5(c), but on page 18, DTSC states that OEHHA complies with HSC §25356.1.5(c) which requires best available science practices.

Response. DTSC has reviewed the responses and determined that there is no contradiction. In general, when deriving toxicity criteria OEHHA strives to comply with HSC §25356.1.5(c); however, several of OEHHA’s older toxicity criteria do not comply with HSC §25356.1.5(c), and so, in consultation with OEHHA, these values were omitted from or later removed from Appendix I. DTSC collaborated with OEHHA to identify the criteria that meet HSC §25356.1.5 and §57004, as reflected in Supplement 1. Please also see the response to comments 18ECO-02 and CBG-14 which further discusses how DTSC worked with OEHHA in developing the values included in Appendix I.

Comment RIN-02. The commenter is concerned that at times the toxicity criteria in Appendix I are the most protective criteria between OEHHA and IRIS but at times a less protective IRIS value or a less protective OEHHA value is recommended.

Response. As explained in the comment response in the Comment Categories “Best Available Science – General,” “Requested Revisions to Appendix I,” and “Basis for Toxicity Criteria,” DTSC specifically applies best available science criteria in accordance with HSC §25356.1.5 and §57004. For contaminants where peer-reviewed values are

available from both OEHHA and IRIS and those values are otherwise equivalent in meeting best available science requirements, DTSC selects the more protective value to reflect California-specific considerations of protectiveness. However, if a more stringent OEHHA value does not meet the conditions in HSC §25356.1.5 and §57004, that value cannot be used, and therefore is not provided in Appendix I.

Comment RIN-03. The commenter is concerned that toxicity criteria chosen by the Supervising HERO toxicologist under 69021(c) are made on a judgement call, and thus there can be room for error or “can undercut the quality of life if the wrong choice is made.”

Response. To the extent that this comment requests revision of the rule to clarify how DTSC will approve or select toxicity criteria in §69021(c), DTSC will continue to comply with HSC §25356.1.5, and does not believe that it is necessary to revise the rule to duplicate those statutory requirements because that section is already referenced in the proposed rule. As explained in the comment response in the Comment Category “Toxicity Criteria Approval-§69021(c)” in Attachment 1, the determination of toxicity criteria under §69021(c) will be consistent with current practice using, to the extent available, “other” sources of toxicity criteria and will be listed in a forthcoming HHRA Note for reference. 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. The HERO Supervising Toxicologist, or designee, will review the available toxicity criteria for a given contaminant from the other sources and in consultation with OEHHA, select the toxicity criteria that best meet the conditions consistent with HSC §25356.1.5 and §57004. More detailed information is described in the comment response in the Comment Category “Toxicity Criteria Approval-§69021(c),” the FSOR, and in the responses to comments CCEEB-14, CCEEB-15, and CMTA-36 above.

Comment RIN-04. The commenter provided a comparison table of the CSFo listed in Appendix I and requests clarification as to why the cell under the CSFo for methylene chloride in Appendix I is left blank. Additionally, the commenter pointed out: 1) that for several chemicals the less stringent toxicity criteria was selected; 2) for several chemicals there is no available OEHHA or IRIS toxicity criteria and thus the impact of the toxicity criteria cannot be assessed; and 3) the toxicity criteria removed from Appendix I were both more and less stringent or had no listed toxicity criteria.

Response. DTSC appreciates the effort made by the commenter in compiling the comparison table of the CSFo. DTSC offers the following specific responses to the criteria in the table.

1. The cell for methylene chloride CSFo was accidentally left blank and should have listed “- -”. DTSC will add “- -” to Appendix I. While OEHHA lists a CSFo, the toxicity criteria is from the September 1985 U.S. EPA Addendum to the Health Assessment Document for Dichloromethane (Methylene Chloride, Updated Carcinogenicity Assessment of Dichloromethane (Methylene Chloride

(<https://nepis.epa.gov/Exe/ZyPDF.cgi/2000BF0O.PDF?Dockkey=2000BF0O.PDF>), and not an OEHHA value. U.S. EPA updated their CSFo in November 2011. Per DTSC's consultation with OEHHA, the CSFo for bromoform and chlordane do not meet the provisions described in HSC §25356.1.5 and §57004 and thus had to be removed from Appendix I; please see Supplement 1 (at the end of these comment responses) which shows those values that qualified for inclusion in Appendix I.

2. The carbon tetrachloride CSFo is a route to route extrapolated value based on the inhalation unit risk, and U.S. EPA released a CSFo for carbon tetrachloride in March 2010. Appendix I lists the CSFo for N-nitroso-di-di-n-butylamine (please note in the table provided there is a typo as the contaminant is listed as "N-nitrosod-di-n-butylamine"). In the table provided by the commenter, the correct value is listed in the second and third columns but incorrectly in the fourth column, and is off by a factor of 100, causing the IRIS value to be highlighted.
3. Finally, as the commenter noted, DTSC had initially listed the OEHHA CSFo for four chemicals (e.g., 1,3-, 1,3-cis- and 1,3-trans-dichloropropene and vinyl chloride) when the IRIS CSFo's are more stringent, and these were removed from Appendix I in the proposed rule released for public comment on April 6, 2018. For additional information, please see the comment response in the Comment Category "Requested Revisions to Appendix I" in Attachment 1. For those chemicals where neither OEHHA nor IRIS lists toxicity criteria, DTSC will continue its current practice and use the criteria from the sources listed under §69021(c) and currently in use for the DTSC screening levels and U.S. EPA regional screening levels. More detailed information is described in the comment response in the Comment Category "Toxicity Criteria Approval-§69021(c)," the FSOR, and in the responses to comments RIN-03, CCEEB-14, CCEEB-15, and CMTA-36 above.

Comment RIN-05. The commenter provided a comparison table of the IURs listed in Appendix I. The commenter states that he was unable to find the source for the hexachlorodibenzo-p-dioxin toxicity criteria value listed, and that the toxicity criteria is less stringent than IRIS. Additionally, the commenter points out that for several chemicals the less stringent toxicity criteria was selected, for several chemicals there is no available OEHHA or IRIS toxicity criteria, and thus the impact of the toxicity criteria cannot be assessed, and the toxicity criteria removed from Appendix I were both more and less stringent or had no listed toxicity criteria.

Response. DTSC appreciates the effort made by the commenter and offers the following specific responses to the entries in the table:

1. Regarding hexachlorodibenzo-p-dioxin IUR, it is on page 152 of the supporting document provided as a curtesy on DTSC's website and can be found at <https://oehha.ca.gov/media/downloads/crn/appendixb.pdf>. DTSC relies on the toxicological expertise of OEHHA for development of the toxicity criteria. Additionally, please note that the OEHHA IUR is more stringent than the IRIS value, 3.8 per $\mu\text{g}/\text{m}^3$ compared to 1.3 per $\mu\text{g}/\text{m}^3$, respectively.

2. OEHHA does not have an IUR for 1,3-, 1,3-cis-, and 1,3-trans-dichloropropene. The toxicity criteria listed in the commenter's table is from the Department of Pesticide Regulation and did not go through a peer review process similar to the process used by OEHHA, as per DTSC's conversations with OEHHA staff (please see Supplement 1 at the end of these comment responses).
3. As explained in DTSC's response in the Comment Category "Best Available Science – General" in Attachment 1, the 2013 IRIS IUR for 1,4-dioxane represents the current scientific knowledge on the toxicity of 1,4-dioxane compared to the 1989 OEHHA value, as it is based on multiple tumors and tumor sites from inhalation exposure and uses updated pharmacokinetic modeling.
4. Regarding 2,4,6-trichlorophenol, the commenter's table identified that the IRIS IUR is more stringent than the OEHHA value; however, the value listed in the table is for the CSFo and not the IUR. The IRIS IUR for 2,4,6-trichlorophenol is 3.1×10^{-6} per $\mu\text{g}/\text{m}^3$ while the OEHHA value is 2×10^{-5} per $\mu\text{g}/\text{m}^3$ and more stringent than the IRIS IUR.
5. Finally, as the commenter noted, in the August Proposed Rule, DTSC had inadvertently listed the OEHHA IUR for arsenic when the IRIS IUR is more stringent. Because of this the arsenic IUR was removed from Appendix I in the April Proposed Rule. For further details, please see the comment response in the Comment Category "Requested Revisions to Appendix I" in Attachment 1. For those chemicals where neither OEHHA nor IRIS lists toxicity criteria, please see the response to comments for RIN-04 above.

Comment RIN-06. The commenter has provided a comparison table of the oral reference doses (RfD) listed in Appendix I. The commenter points out that for one chemical the less stringent toxicity criteria was selected, for several chemicals there is no available OEHHA or IRIS toxicity criteria and thus the impact of the toxicity criteria cannot be assessed, and the toxicity criteria removed from Appendix I were both more and less stringent criteria. Additionally, the commenter was not able to locate the cited RfD for beryllium.

Response. DTSC appreciates the effort made by the commenter and offers the following specific responses to the entries in the table:

1. Please note that the beryllium RfD is provided on page 154 of the supporting document provided as a courtesy on DTSC's website and can be found at: <http://dtsc.ca.gov/LawsRegsPolicies/Regs/upload/7-Beryllium-and-compounds.pdf>.
2. For several of the chemicals identified in the commenter's table (e.g., cadmium, chlordane, and manganese [non-dietary]), the commenter cited the OEHHA child-specific reference dose, which is different than the other OEHHA RfDs in Appendix I. The OEHHA child-specific reference doses are specific for use in risk assessment of proposed or existing California school sites. Please note that for the other chemicals removed from Appendix I an OEHHA RfD was not listed in

the August Proposed Rule. For those chemicals where neither OEHHA nor IRIS lists toxicity criteria, please see the response to comments for RIN-04 above.

Comment RIN-07. The commenter has provided a comparison table of the chronic inhalation reference exposure levels (RELs) listed in Appendix I. The commenter points out that for one chemical the less stringent toxicity criteria was selected, for several chemicals there is no available OEHHA or IRIS toxicity criteria and thus the impact of the toxicity criteria cannot be assessed, and the toxicity criteria removed from Appendix I were both more and less protective criteria.

Response. DTSC appreciates the effort made by the commenter and offers the following specific responses to the entries in the table:

1. As the commenter notes, the August Proposed Rule included the OEHHA REL for two chemicals, epichlorohydrin and manganese (non-dietary) even though the IRIS reference concentrations were more stringent; thus, these two chemicals were removed from Appendix I that was provided in the April Proposed Rule. For additional information, please see the comment response in the Comment Category “Requested Revisions to Appendix I” in Attachment 1.
2. The REL for 2-butoxyethanol listed in the OEHHA database, at the time DTSC released the April Proposed Rule, had not been officially adopted and was still under review by the Scientific Review Panel. On May 4, 2018 OEHHA officially adopted the REL for 2 butoxyethanol; however, DTSC is not able to include it in Appendix I, since adoption was after the formal comment period on the revised proposed rule. After approval and adoption of this rule, DTSC intends to regularly amend the rule appropriately. This action is discussed in the comment responses in the Comment Category “Updating the Rule” in Attachment 1 and f the FSOR. Please note that for the remaining chemicals removed from Appendix I, an OEHHA REL was not listed in the August Proposed Rule. For those chemicals where neither OEHHA nor IRIS lists toxicity criteria, please see the response to comments for RIN-04 above.

Rocketdyne Cleanup Coalition

Below are responses to comments from Rocketdyne Cleanup Coalition (RCC).

Comment RCC-01. The commenter expressed concerns that the April Proposed Rule “weakens” the August Proposed Rule, which the commenter felt was already inadequate to protect public health. The commenter expresses distrust with DTSC and disapproval of prior DTSC decisions.

Response. DTSC is committed to protect California’s people and environment from harmful effects of toxic substances by restoring contaminated resources, enforcing hazardous waste laws, reducing hazardous waste generation, and encouraging the manufacture of chemically safer products. While the majority of the comment is not

related to the proposed rule, DTSC is open to further dialog with RCC to address the commenter's views of DTSC's work.

The commenter did not identify specific concerns about the April Proposed Rule compared to the August Proposed Rule and so, to the extent the comment pertains to selection of certain toxicity criteria values, please see DTSC's response to "Derivation of Toxicity Criteria" and "Best Available Science" in Attachment 1 and to 18ECO-01, 18ECO-02, CCEEB-13, and CBG-11 above.

Comment RCC-02. The commenter asserts that DTSC held a meeting in December 2016 with lobbyists and other representatives of polluting interests before redrafting the proposed rule for formal public input. Furthermore, since the meeting was held in Sacramento, "everyday victims of DTSC's policies...could not readily attend" and DTSC "caved" to the polluters.

Response. Based on the month and year provided, DTSC presumes the commenter is referring to the "pre-APA" workshop held in Sacramento on December 12, 2016, which was not part of the formal rulemaking process. DTSC conducted the December 2016 workshop as a listening session on the regulatory concept with a sincere desire to collect and address concerns from all interested parties and meet the objectives of the proposed rule within the bounds of DTSC's legal authority.

As discussed in the ISOR, DTSC made changes reflected in the proposed rule in response to feedback in the December 12, 2016 workshop, written and verbal comments from the public on the pre-APA draft rule, and recognition that changes were needed to meet requirements under various California Health and Safety Code sections, and U.S. EPA guidance.

DTSC further notes that: 1) the December 2016 workshop was publicly noticed for all members of the public to attend; 2) the meeting was webcast live for the public who could not attend in person to observe; and 3) comments from the public on the "pre-APA" version of the rule concept were solicited via the workshop notice and verbally during the workshop.

Comment RCC-03. The commenter states that the August Proposed Rule was severely weakened compared to the pre-APA version.

Response. DTSC made some revisions to the August Proposed Rule in order to comply with existing law and/or guidance as noted above. Please see the responses to comments 18ECO-01, -02, CCEEB-13, and CBG-11 which addresses the commenter's concern.

Comment RCC-04. The commenter states that there were no hearings in Southern California and asserts that one was promised.

Response. Please note that, as mentioned above, DTSC did conduct a workshop in Southern California, as well as a webcast open to the entire state and internet and did not promise to hold a public hearing in Southern California. Note that APA requirements do not specify more than one public hearing. Also, note that DTSC held three public workshops, including one in Southern California, and provided two public comment periods for the proposed rule to obtain input as much as reasonably possible from all interested parties. DTSC also provided webcasting of the public hearing on September 20, 2017 to allow interested parties to view and to enhance statewide public participation. A full listing of public outreach is discussed in the response to comment PSRLA-01 above.

Comment RCC-05. The commenter states that certain toxicity criteria in Appendix I of the August Proposed Rule were not in the April Proposed Rule and that the most protective criteria of the available criteria sources should be incorporated into the rule.

Response. DTSC believes that making such a revision to the rule would be contrary to existing law and/or guidance as noted in other responses to 18ECO-01, 18ECO-02, and CBG-13 comments. DTSC agrees that certain criteria were removed from Appendix I because of legal requirements to use the best available science. Please see the response to comment CBG-11 for an explanation of why certain toxicity criteria were removed from Appendix I and the response to comments 18ECO-01 and 18ECO-02 for how toxicity criteria are selected for incorporation into the rule.

Comment RCC-06. The commenter asserts that the determination of which toxicity criteria will be incorporated into the proposed rule will be subjective and weakens the rule.

Response. DTSC's scientific evaluation of toxicity criteria is subject to statutory requirements set by the Legislature in §25356.1.5 and HSC §57004. Please see the responses to comments 18ECO-01 and 18ECO-02, which provide information on how toxicity criteria were selected for incorporation into the proposed rule, and responses to comments 18ECO-02 and CBG-13 for information on OEHHA and DTSC's roles and responsibilities in developing and selecting toxicity criteria for risk assessments at hazardous waste and substance release sites in California.

Comment RCC-07. The commenter asserts that DTSC should not select toxicity criteria, and that only OEHHA should select toxicity criteria.

Response. DTSC disagrees with the comment and would like to note that DTSC staff closely collaborated with OEHHA staff in developing this rule and the selection of toxicity criteria in Appendix 1. For an explanation, please see the responses to comments 18ECO-02 and CBG-13 for information on OEHHA and DTSCs' roles and responsibilities in developing and selecting toxicity criteria for risk assessments at hazardous waste and substance release sites in California.

Comment RCC-08. The commenter objects to the inclusion of “anticipated land use” in the proposed rule.

Response. For a discussion of this concern, please see responses above to comments 18ECO-03, CBG-16, and PSRLA-03.

Ms. Laura Rosenberger Haider

While received separately, Ms. Laura Rosenberger Haider’s comments are essentially the same as those from “18 Environmental Coalitions and Organizations.” Accordingly, Ms. Rosenberger Haider’s comments are addressed by the responses to the comments from “18 Environmental Coalitions and Organizations” above.

Rootskeeper

While received separately, Rootskeeper’s comments are essentially the same as those from “18 Environmental Coalitions and Organizations.” Accordingly, Rootskeeper’s comments are addressed by the responses to the comments from “18 Environmental Coalitions and Organizations” above.

Seven Commerce Organizations

Although these comments were received 26 days after the close of the comment period, in the interest of addressing all comments, DTSC provides the following responses to comments from the Seven Commerce Organizations (SCO).

Comment SCO-01. The commenter requests that Section 69021 (c) be modified so that alternative toxicity criteria may be used if DTSC determines they are “more scientifically appropriate.”

Response. DTSC does not believe that it is appropriate to revise the proposed rule based on this comment. The rule requires compliance with the statutory requirements set by the Legislature in §25356.1.5, which already requires best available science, methods and practices.

Comment SCO-2. The commenter requests changes to §69022(c) to clarify that the NCP risk range applies during the risk assessment and remedy selection.

Response. The first part of the comment requests that §69022 state that the risk range applies during the risk assessment. DTSC does not believe that it is appropriate or necessary to make this change because it conflicts with federal guidance, and therefore also conflicts with HSC §25356.1.5. As discussed in U.S. EPA *Interim Final Risk Assessment Guidance for Superfund (RAGS) Volume I, Human Health Evaluation Manual (Part A)*, the risk assessment is completed before using the risk range in risk

management decisions. It is during the risk management phase that the risk range is used and remedial goals are selected.

The second part of the comment requests that §69022 state that the risk range applies during remedy selection. This issue has, in essence, been expressed repeatedly in various forms by other commenters as loss of flexibility, or concern that risk managers may interpret the rule to require that remediation goals be set at screening levels. The commenter is requesting informative statements that do not change the rule be added to the rule text which is contrary to general rule text format. The proposed rule intent is clear on face value which is the selection of appropriate toxicity criteria for use in risk assessments and setting risk-based screening levels and remediation goals. The rule is consistent with the NCP, and remediation goals under CERCLA will continue to be developed in accordance with the NCP. To further address this concern, DTSC will provide additional guidance and outreach on how to apply the rule and which will reiterate the rule neither requires nor prohibits the remediation goal from being set at the screening level for any site or contaminant and that DTSC will continue to use the risk range in risk-management decisions pursuant to the NCP and other related statutes and regulations.

Also please see specific responses to comments CCEEB-16, CMTA-57, COC-07, and L&W-06.4.

Comment SCO-03. The commenter requests the removal of the OEHHA IUR for benzo(a)pyrene based on the commenter's belief that DTSC agreed that the 2017 IRIS values represent the best available science.

Response. DTSC's comment regarding the 2017 IRIS value in Attachment 1 is in reference to the CSFo not the IUR. DTSC recommends using the 2017 IRIS CSFo for benzo(a)pyrene not only because it represents best available science but also because the OEHHA CSFo value from the 2010 public health goal did not go through a peer review. While the IRIS IUR toxicity criteria value for benzo[a]pyrene is more recent than the corresponding OEHHA value, the "older" but more stringent OEHHA criteria is specified in the proposed rule because it satisfies the best available science provisions of HSC §25356.1.5 and §57004.

Southern California Federation of Scientists

Below are responses to comments from Southern California Federation of Scientists (SCSF).

Comment SCSF-01. The commenter asserts that the April Proposed Rule weaker than the pre-APA" version of the proposed rule and that the rule should apply the most protective of corresponding OEHHA or IRIS values for each contaminant.

Response. DTSC believes that it is not appropriate to make the revisions requested because they would be contrary to existing law and/or guidance as noted in other DTSC responses to comments. Please see the response to comments CBG-10 and CBG-11

on the concern that the rule has been “weakened” and responses to comments 18ECO-01 18ECO-02, and CCEEB-13 above on the concern that the rule should apply the most protective toxicity criteria of the listed sources.

Comment SCSF-02. The commenter states that the rule will “give to DTSC the ability and authority to second-guess OEHHA and EPA, rejecting the more protective value” and “DTSC should not usurp OEHHA’s role.”

Response. DTSC believes that it is not appropriate to change the rule based on this comment, because of the statutory requirements set by the Legislature in §25356.1.5 and HSC §57004. Please see the response to comment 18ECO-02 for a discussion of OEHHA and DTSC’s responsibilities in developing toxicity criteria and selecting toxicity criteria for human health risk assessments, screening levels, and remediation goals for hazardous waste and substance release sites in California.

REFERENCES

California Office of Environmental Health Hazard Assessment, Air Toxicology and Epidemiology Branch. *Technical Support Document for Cancer Potency Factors: Appendix B: Chemical-Specific Summaries of the Information Used to Derive Unit Risk and Cancer Potency Values.* (January 2011).
<<https://oehha.ca.gov/media/downloads/crn/appendixb.pdf>> (as of May 8, 2018).

Spearow, J., Gettmann, K., and Wade, M. *Review: Risk Assessment Implications of Variation in Susceptibility to Perchloroethylene Due to Genetic Diversity, Ethnicity, Age, Gender, Diet and Pharmaceuticals*, Human and Ecological Risk Assessment: An International Journal. (2017). <available online at
<http://www.tandfonline.com/doi/full/10.1080/10807039.2017.1327799>>.

U.S. Environmental Protection Agency. *Superfund (RAGS) Volume I, Human Health Evaluation Manual (Part A).* (1989) <https://www.epa.gov/sites/production/files/2015-09/documents/rags_a.pdf> (as of January 26, 2017).

U.S. Environmental Protection Agency. Health Assessment of 1,3-Butadiene. U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington Office, Washington, DC, EPA/600/P-98/001F, 2002.
<https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0139_summary.pdf> (as of May 8, 2018).

U.S. Environmental Protection Agency. Addendum to the Health Assessment Document for Dichloromethane (Methylene Chloride, Updated Carcinogenicity Assessment of Dichloromethane (Methylene Chloride)
<<https://nepis.epa.gov/Exe/ZyPDF.cgi/2000BF00.PDF?Dockey=2000BF00.PDF>> (as of May 8, 2018).

U.S. Environmental Protection Agency. Office of Solid Waste and Emergency Response (OSWER) Directive 9285.7-53. *Human Health Toxicity Values in Superfund Risk Assessment*. (2003). <<https://rais.ornl.gov/documents/hhmemo.pdf>> (as of January 26, 2017).

Toxicity Criteria Rulemaking Package

Index to the Responses to Comments on the April 2018 Proposed Rule

Commenter	Comment Number	Response Page Number
African American Caucus of the League of California Cities	(a)	6
Ms. Cheryl Brown	(a)	6
18 Environmental Coalitions and Organizations	18ECO-01	6
18 Environmental Coalitions and Organizations	18ECO-02	6
18 Environmental Coalitions and Organizations	18ECO-03	7
Ms. Joni Arends	(b)	7
California Council for Environmental and Economic Balance	CCEEB-12	8
California Council for Environmental and Economic Balance	CCEEB-13	8
California Council for Environmental and Economic Balance	CCEEB-14	8
California Council for Environmental and Economic Balance	CCEEB-15	9
California Council for Environmental and Economic Balance	CCEEB-16	10
California Council for Environmental and Economic Balance	CCEEB-17	10
California Council for Environmental and Economic Balance	CCEEB-18	11
California Manufacturers and Technology Association	CMTA-31	12
California Manufacturers and Technology Association	CMTA-32	12
California Manufacturers and Technology Association	CMTA-33	12
California Manufacturers and Technology Association	CMTA-34	13
California Manufacturers and Technology Association	CMTA-35	13
California Manufacturers and Technology Association	CMTA-36	14
California Manufacturers and Technology Association	CMTA-37	14
California Manufacturers and Technology Association	CMTA-38	15
California Manufacturers and Technology Association	CMTA-39	15
California Manufacturers and Technology Association	CMTA-40	16
California Manufacturers and Technology Association	CMTA-41	16
California Manufacturers and Technology Association	CMTA-42	16
California Manufacturers and Technology Association	CMTA-43	17
California Manufacturers and Technology Association	CMTA-44	17
California Manufacturers and Technology Association	CMTA-45	17
California Manufacturers and Technology Association	CMTA-46	18
California Manufacturers and Technology Association	CMTA-47	18
California Manufacturers and Technology Association	CMTA-48	18
California Manufacturers and Technology Association	CMTA-49	18
California Manufacturers and Technology Association	CMTA-50	18
California Manufacturers and Technology Association	CMTA-51	19
California Manufacturers and Technology Association	CMTA-52	19
California Manufacturers and Technology Association	CMTA-53	19
California Manufacturers and Technology Association	CMTA-54	19
California Manufacturers and Technology Association	CMTA-55	20
California Manufacturers and Technology Association	CMTA-56	20
California Manufacturers and Technology Association	CMTA-57	20
California Manufacturers and Technology Association	CMTA-58	21

Toxicity Criteria Rulemaking Package

Index to the Responses to Comments on the April 2018 Proposed Rule

Commenter	Comment Number	Response Page Number
California Manufacturers and Technology Association	CMTA-59	21
California Manufacturers and Technology Association	CMTA-60	22
California Manufacturers and Technology Association	CMTA-61	23
City of Compton	COC-01	23
City of Compton	COC-02	23
City of Compton	COC-03	24
City of Compton	COC-04	24
City of Compton	COC-05	24
City of Compton	COC-06	24
City of Compton	COC-07	25
City of Compton	COC-08	25
Committee to Bridge the Gap	CBG-10	25
Committee to Bridge the Gap	CBG-11	25
Committee to Bridge the Gap	CBG-12	26
Committee to Bridge the Gap	CBG-13	26
Committee to Bridge the Gap	CBG-14	27
Committee to Bridge the Gap	CBG-15	27
Committee to Bridge the Gap	CBG-16	27
Fresh Air Vallejo	(b)	28
U.S. Department of the Navy (Department of Defense)	DOD-20	28
Fort Ord Environmental Justice Network	(b)	28
Latham & Watkins, LLP	L&W-06	29
Physicians for Social Responsibility-Los Angeles	PSRLA-01	34
Physicians for Social Responsibility-Los Angeles	PSRLA-02	34
Physicians for Social Responsibility-Los Angeles	PSRLA-03	35
Physicians for Social Responsibility-Los Angeles	PSRLA-04	35
Mr. Michael Rincon	RIN-01	35
Mr. Michael Rincon	RIN-02	35
Mr. Michael Rincon	RIN-03	36
Mr. Michael Rincon	RIN-04	36
Mr. Michael Rincon	RIN-05	37
Mr. Michael Rincon	RIN-06	38
Mr. Michael Rincon	RIN-07	39
Rocketdyne Cleanup Coalition	RCC-01	39
Rocketdyne Cleanup Coalition	RCC-02	40
Rocketdyne Cleanup Coalition	RCC-03	40
Rocketdyne Cleanup Coalition	RCC-04	40
Rocketdyne Cleanup Coalition	RCC-05	41
Rocketdyne Cleanup Coalition	RCC-06	41
Rocketdyne Cleanup Coalition	RCC-07	41
Rocketdyne Cleanup Coalition	RCC-08	42

Toxicity Criteria Rulemaking Package

Index to the Responses to Comments on the April 2018 Proposed Rule

Commenter	Comment Number	Response Page Number
Mr. Laura Rosenberger Haider	(b)	42
Rootskeeper	(b)	42
Seven Commerce Organizations	SCO-01	42
Seven Commerce Organizations	SCO-02	42
Seven Commerce Organizations	SCO-03	43
Southern California Federation of Scientists	SCSF-01	43
Southern California Federation of Scientists	SCSF-02	44

(a) = Comments were addressed by responses to the City of Compton

(b) = Comments were addressed by responses to the 18 Environmental Coalitions and Organizations

DRAFT Appendix I. California OEHHA-based Toxicity Criteria - Reviewed by OEHHA

Line #	Analyte	CAS Registry Number	Cancer Potency Values				Non-cancer Health-Hazard Values			
			Oral Slope Factor (CSF _o)		Inhalation Unit Risk (IUR)		Oral Reference Dose (RfD _o)		Chronic Reference Exposure Level (REL)	
			CSF _o (mg/kg-d) ⁻¹	Reference	IUR (µg/m ³) ⁻¹	Reference	RfDo (mg/kg-d)	Reference	REL or RfC (µg/m ³)	Reference
1	Acetaldehyde	75-07-0	--	--	2.70E-06	OEHHA	--	--	--	--
2	Ammonia	7664-41-7	--	--	--	--	--	--	2.00E+02	OEHHA
3	Arsenic	7440-38-2	9.50E+00	OEHHA PHG	3.30E-03	OEHHA	3.50E-06	OEHHA	1.50E-02	OEHHA
4	Arsine	7784-42-1	--	--	--	--	3.50E-06	OEHHA	1.50E-02	OEHHA
5	Benzene	71-43-2	1.00E-01	OEHHA	2.90E-05	OEHHA	--	--	3.00E+00	OEHHA
6	Benzidine	92-87-5	5.00E+02	OEHHA	1.40E-01	OEHHA	--	--	--	--
7	Benzo[a]anthracene	56-55-3	--	--	1.10E-04	OEHHA	--	--	--	--
8	Benzo[a]pyrene	50-32-8	--	--	1.10E-03	OEHHA	--	--	--	--
9	Benzo[b]fluoranthene	205-99-2	--	--	1.10E-04	OEHHA	--	--	--	--
10	Benzo[k]fluoranthene	207-08-9	--	--	1.10E-04	OEHHA	--	--	--	--
11	Beryllium	7440-41-7	--	--	--	--	2.00E-04	OEHHA PHG	7.00E-03	OEHHA
12	Beryllium oxide	1304-56-9	--	--	--	--	2.00E-04	OEHHA PHG	7.00E-03	OEHHA
13	Beryllium sulfate	13510-49-1	--	--	--	--	2.00E-04	OEHHA PHG	7.00E-03	OEHHA
14	Boron Trifluoride	7637-07-2	--	--	--	--	4.00E-02	OEHHA (Fluorides)	--	--
15	Bromoform	75-25-2	1.10E-02	OEHHA	--	--	--	--	--	--
16	1,3-Butadiene	106-99-0	6.00E-01	OEHHA	1.70E-04	OEHHA	--	--	2.00E+00	OEHHA
17	2-Butoxyethanol	111-76-2	--	--	--	--	--	--	8.20E+01	OEHHA
18	Cadmium	7440-43-9	--	--	4.20E-03	OEHHA	--	--	--	--
19	Carbon tetrachloride	56-23-5	1.50E-01	OEHHA	4.20E-05	OEHHA	--	--	4.00E+01	OEHHA
20	Carbonyl sulfide	463-58-1	--	--	--	--	--	--	1.00E+01	OEHHA
21	Chlordane	57-74-9	1.30E+00	OEHHA	3.40E-04	OEHHA	--	--	--	--
22	Chromium (VI)	18540-29-9	5.00E-01	OEHHA PHG	1.50E-01	OEHHA	--	--	--	--
23	Chrysene	218-01-9	--	--	1.10E-05	OEHHA	--	--	--	--
24	Dibenz[a,h]anthracene	53-70-3	4.10E+00	OEHHA ECP	1.20E-03	OEHHA	--	--	--	--
25	3,3'-Dichlorobenzidine	91-94-1	1.20E+00	OEHHA	3.40E-04	OEHHA	--	--	--	--
26	1,1-Dichloroethene	75-35-4	--	--	--	--	--	--	7.00E+01	OEHHA
27	1,3-Dichloropropene	542-75-6	9.10E-02	OEHHA	1.60E-05	OEHHA	--	--	--	--

IUR removed in 4/6/2018 version of Appendix I - IRIS IUR more stringent than OEHHA

CSFo removed in 4/6/2018 version of Appendix I, per conversation with OEHHA 9/7/2017 - did not go through peer review

Removed - was finalized on 5/4/2018 after DTSC removed it from Appendix I in revised draft version of regulation that went out for public comment on 4/6/2018

CSFo and IUR removed in 4/6/2018 version of Appendix I - IRIS value new based on better science

CSFo and IUR removed in 4/6/2018 version of Appendix I, per conversation with OEHHA 9/7/2017 - did not go through proper peer review - email confirmation from F. Krammerer on 9/7/2017

CSFo and IUR removed in 4/6/2018 version of Appendix I, per conversation with OEHHA 9/7/2017 - did not go through proper peer review - email confirmation from F. Krammerer on 9/7/2017. Additionally OEHHA CSFo is less protective than IRIS and IUR is from DPR not derived by OEHHA.

DRAFT Appendix I. California OEHHA-based Toxicity Criteria - Reviewed by OEHHA

Line #	Analyte	CAS Registry Number	Cancer Potency Values				Non-cancer Health-Hazard Values				
			Oral Slope Factor (CSF _o)		Inhalation Unit Risk (IUR)		Oral Reference Dose (RfD _o)		Chronic Reference Exposure Level (REL)		
			CSF _o (mg/kg-d) ⁻¹	Reference	IUR (µg/m ³) ⁻¹	Reference	RfD _o (mg/kg-d)	Reference	REL or RfC (µg/m ³)	Reference	
28	cis-1,3-Dichloropropene	10061-01-5	9.10E-02	OEHHA (1,3-Dichloropropene)	1.60E-05	OEHHA (1,3-Dichloropropene)	--	--	--	--	CSF _o and IUR removed in 4/6/2018 version of Appendix I, per conversation with OEHHA 9/7/2017
29	trans-1,3-Dichloropropene	10061-02-6	9.10E-02	OEHHA (1,3-Dichloropropene)	1.60E-05	OEHHA (1,3-Dichloropropene)	--	--	--	--	CSF _o and IUR removed in 4/6/2018 version of Appendix I, per conversation with OEHHA 9/7/2017
30	1,4-Dioxane	123-91-1	--	--	7.70E-06	OEHHA	--	--	--	--	IUR removed in 4/6/2018 version of Appendix I - IRIS value based on better science EPA has an oral slope factor and an inhalation unit risk.
31	Epichlorohydrin	106-89-8	8.00E-02	OEHHA	2.30E-05	OEHHA	--	--	3.00E+00	OEHHA	REL removed in 4/6/2018 version of Appendix I - IRIS RfC more stringent than OEHHA
32	bis(2-Chloroethyl) ether	111-44-4	2.50E+00	OEHHA	7.10E-04	OEHHA	--	--	--	--	
33	Ethylene dibromide	106-93-4	--	--	--	--	--	--	8.00E-01	OEHHA	
34	Formaldehyde	50-00-0	--	--	--	--	--	--	9.00E+00	OEHHA	
35	HCH (mixed isomers)	608-73-1	4.00E+00	OEHHA	1.10E-03	OEHHA	--	--	--	--	
36	Hexachlorobenzene	118-74-1	1.80E+00	OEHHA	5.10E-04	OEHHA	--	--	--	--	
37	Hexachlorodibenzo-p-dioxin Mixture (2:1 1,2,3,7,8,9- and 1,2,3,6,7,8-)	Hexachlorodibenzo-p-dioxin Mixture	--	--	3.80E+00	OEHHA (WHO-05 TEF)	--	--	--	--	
38	Hydrochloric acid	7647-01-0	--	--	--	--	--	--	9.00E+00	OEHHA	
39	Indeno[1,2,3-cd]pyrene	193-39-5	--	--	1.10E-04	OEHHA	--	--	--	--	
40	Lead and compounds ^f	7439-92-1	--	--	--	--	1.0 ug/dL	OEHHA	--	--	
41	Lead subacetate	1335-32-6	3.80E-02	OEHHA	1.10E-05	OEHHA	--	--	--	--	CSF and IUR peer reviewed through TAC and HS Cancer TSD per email communication with OEHHA on 5/14/2018.
42	Manganese (non-diet)	7439-96-5 (non-diet)	--	--	--	--	--	--	9.00E-02	OEHHA	REL removed in 4/6/2018 version of Appendix I - IRIS RfC more stringent than OEHHA
43	Mercuric Chloride	7487-94-7	--	--	--	--	1.60E-04	OEHHA REL	3.00E-02	OEHHA	
44	Mercury	7439-97-6	--	--	--	--	1.60E-04	OEHHA REL	3.00E-02	OEHHA	
45	Methylene Chloride	75-09-2	--	--	1.00E-06	OEHHA	--	--	4.00E+02	OEHHA	
46	4,4'-Methylene-bis(2-chloroaniline)	101-14-4	1.50E+00	OEHHA	--	--	--	--	--	--	IRIS does not have a IUR and EPA uses OEHHA's value, will be listed in the HHRA Note table for 69021c
47	Methylene diphenyl diisocyanate	101-68-8	--	--	--	--	--	--	8.00E-02	OEHHA	OEHHA has a MOCA IUR of 4.30E-04
48	Polymeric methylenediphenyl diisocyanate	9016-87-9	--	--	--	--	--	--	8.00E-02	OEHHA	
49	Mirex	2385-85-5	1.80E+01	OEHHA	5.10E-03	OEHHA	--	--	--	--	CSF _o and IUR removed in final version of Appendix I, per conversation with OEHHA on 5/9/2018 - did not go through proper peer review
50	1-Naphthylamine	134-32-7	1.80E+00	OEHHA	--	--	--	--	--	--	CSF _o removed in final version of Appendix I, per conversation with OEHHA on 5/9/2018 - did not go through proper peer review
51	Nickel	7440-02-0	--	--	2.60E-04	OEHHA	1.10E-02	OEHHA	1.40E-02	OEHHA	
52	Nickel Hydroxide	12054-48-7	--	--	2.60E-04	OEHHA	1.10E-02	OEHHA	1.40E-02	OEHHA	
53	Nickel Oxide	1313-99-1	--	--	2.60E-04	OEHHA	1.10E-02	OEHHA	2.00E-02	OEHHA	
54	Nickel refinery dust	Nickel refinery dust	--	--	2.60E-04	OEHHA	1.10E-02	OEHHA	1.40E-02	OEHHA	
55	Nickel subsulfide	12035-72-2	--	--	--	--	1.10E-02	OEHHA	1.40E-02	OEHHA	
56	N-Nitroso-di-n-butylamine	924-16-3	1.10E+01	OEHHA	3.10E-03	OEHHA	--	--	--	--	
57	Styrene	100-42-5	--	--	--	--	--	--	9.00E+02	OEHHA	
58	Tetrachloroethene	127-18-4	5.40E-01	OEHHA PHG	6.10E-06	OEHHA	--	--	--	--	

DRAFT Appendix I. California OEHHA-based Toxicity Criteria - Reviewed by OEHHA

Line #	Analyte	CAS Registry Number	Cancer Potency Values				Non-cancer Health-Hazard Values			
			Oral Slope Factor (CSF _o)		Inhalation Unit Risk (IUR)		Oral Reference Dose (RfD _o)		Chronic Reference Exposure Level (REL)	
			CSF _o (mg/kg-d) ⁻¹	Reference	IUR (µg/m ³) ⁻¹	Reference	RfDo (mg/kg-d)	Reference	REL or RfC (µg/m ³)	Reference
59	Toluene	108-88-3	--	--	--	--	--	--	3.00E+02	OEHHA
60	Toluene 2,4/2,6-Diisocyanates	26471-62-5	3.90E-02	OEHHA	--	--	--	--	8.00E-03	OEHHA
61	Toluene-2,4-diisocyanate	584-84-9	3.90E-02	OEHHA (toluene diisocyanates)	--	--	--	--	8.00E-03	OEHHA (toluene diisocyanates)
62	Toluene-2,6-diisocyanate	91-08-7	3.90E-02	OEHHA (toluene diisocyanates)	--	--	--	--	8.00E-03	OEHHA (toluene diisocyanates)
63	o-Toluidine	95-53-4	1.80E-01	OEHHA	--	--	--	--	--	--
64	Toxaphene	8001-35-2	1.20E+00	OEHHA	--	--	--	--	--	--
65	1,1,1-Trichloroethane	71-55-6	--	--	--	--	--	--	1.00E+03	OEHHA
66	2,4,6-Trichlorophenol	88-06-2	7.00E-02	OEHHA	2.00E-05	OEHHA	--	--	--	--
67	Vinyl chloride	75-01-4	2.70E-01	OEHHA	7.80E-05	OEHHA	--	--	--	--

CSFo removed in final version of Appendix I, per conversation with OEHHA on 5/9/2018 - did not go through proper peer review
2003 PHG peer reviewed

CSFo removed in 4/6/2018 version of Appendix I - IRIS CSFo more stringent than OEHHA

OEHHA has a TDI IUR of 1.10E-05

OEHHA has a TDI IUR of 1.10E-05

OEHHA has a TDI IUR of 1.10E-05

IRIS does not have a IUR and EPA uses OEHHA's value, will be listed in the HHRA Note table for 69021c
IRIS does not have a IUR and EPA uses OEHHA's value, will be listed in the HHRA Note table for 69021c
IRIS does not have a IUR and EPA uses OEHHA's value, will be listed in the HHRA Note table for 69021c

"--" = No recommended OEHHA toxicity value.

ACERB certification

(mg/kg-d)⁻¹ = per (milligram per kilogram--day)

(µg/m³)⁻¹ = per (microgram per cubic meter)

CAS = Chemical Abstracts Service

CSFo = oral slope factor

IUR = inhalation unit-risk factor

OEHHA = California Office of Environmental Health

PHG = Public Health Goal toxicity factor

REL = chronic reference exposure level

RfD = chronic oral reference dose

[#]Lead is expressed as ug/dL (microgram per deciliter) -

in the final Appendix I, located in separate table

WHO-05 TEF = 2005 World Health Organization,

Toxicity Equivalency Factor

- cancer unit risk/slope factors or RELs generated by TAC/Hotspots - values are correct
- cancer unit risk/slope factors generated by P65 but peer reviewed by SRP - values are correct
- not yet finally approved by SRP or adopted by OEHHA as of 9/7/2017. Update- was finalized on 5/4/2018, however DTSC removed it from Appendix I in the revised draft rule that went out for public comment on 4/6/2018. Not included in Final Rule.