

# Comments by the Committee to Bridge the Gap<sup>1</sup> on the Department of Toxic Substances Control's Proposed Regulations for Toxicity Criteria for Human Health Risk Assessment

DTSC Reference Number R-2016-8

20 September 2017

## Introduction

Appropriate toxicity criteria for human health risk assessments are critical for protecting the public from toxic materials. The federal government establishes minimum levels of protection, a floor so to speak, and California policy has long required the use of California standards when more protective than the federal ones. Consistent with this, on 11 November 2016, DTSC proposed regulations, which would have required the use of the most protective toxicity criteria.

DTSC has now, however, backed off from that commitment to public protection and issued a changed proposed rule that no longer would require the use of the most protective standards. Indeed, as shown in our analysis below and in the attached comparison tables we have prepared, for many of the contaminants of concern, the proposed rule would mandate the use of the weakest criteria. No rationale has been provided for this backsliding, nor can there be any.

CBG-01

Furthermore, the new proposed rule is not candid about this weakening of protections. Indeed, the rule's Statement of Reasons says:

CBG-02

The California Department of Toxic Substances Control (Department) is promulgating this (new) rule to adopt Office of Environmental Health Hazard Assessment [footnote omitted] (OEHHA) toxicity criteria listed in Appendix I and require their use *because they afford greater protection of human health, safety and the environment than the nationwide minimum standard provided by analogous federal toxicity criteria for the same contaminants.*

This statement is false. As we have shown in the attached comparison, for many contaminants, the OEHHA toxicity criteria afford lesser, rather than greater protection than the national minimum standards for the same contaminants.<sup>2</sup>

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<sup>2</sup> Indeed, buried elsewhere in the Statement of Reasons, DTSC acknowledges that it initially proposed a rule that would have used the most protective toxicity criteria but in the face of unspecified opposition has now reversed course.

DTSC’s regulation should do what this statement incorrectly says it does – require the use of the most protective standard. We respectfully urge DTSC to return to that principle.

—CBG-02  
(cont.)

### Discussion

For any release of hazardous waste or hazardous constituents, the human health risk assessment calculations, including, but not limited to, all cancer risk and non-cancer risk hazard screening levels and corrective action objectives must use the most protective standards with the best available science. The Department of Toxic Substances Control (DTSC) has submitted a proposal of new Toxicity Criteria for Human health Risk Assessments and Health-Based Decision Making, California Code of Regulations, title 22, sections 69020-69022, which will be used for future human health risk assessments.

—CBG-03

As stated in the proposal itself, these changes apply to cleanups (e.g., response or corrective action) of released hazardous waste or hazardous waste constituents, hazardous materials, and hazardous substances (collectively, hazardous substances) to the environment. Furthermore, it is indicated that section 69021 of this proposal specifies the required toxicity criteria that will be adopted by the department for setting all human health risk-based screening levels and human health risk-based remediation goals, and in all human health risk assessments for those sites.

The proposal expresses the importance of this criteria by stating that the “toxicity criteria are substantive standards of control that provide health-based protection for the entirety of California’s diverse population, including its most sensitive receptors, from harmful exposures to hazardous substance(s) released to the environment.” By following the proposed text of section 69021, “Applicable Toxicity Criteria”, the proposal states “all human health risk assessments, human health risk-based screening levels, and human health risk-based remediation goals used for the cleanup of sites described under section 69020, subdivision (b), *shall* use the cancer and non-cancer toxicity criteria for each contaminant of potential concern (COPC) from the following sources in the order listed below: (a) California Environmental Protection Agency’s Office of Environmental Health Hazard Assessment (OEHHA), (b) U.S. Environmental Protection Agency’s Integrated Risk Information System (IRIS), and (c) DTSC’s Human and Ecological Risk Office (HERO)”.

Section 69021, subdivision (a) then states that OEHHA’s peer reviewed risk values are listed in Appendix 1, which is a table of values for Oral Slope Factors, Inhalation Unit Risk, Oral Reference Dosage, and Reference Exposure Level/Reference Concentration that will be used in the new criteria to “further protect” the general public. It is then stated that any value left blank in Appendix 1, will then get filled by EPA’s IRIS, and lastly by DTSC’s HERO where IRIS can not provide a value. Note that the proposed text lists “other sources” that could be used, though during our review of these sources, we noticed that the “other sources” were already included in the HERO document we used for our value comparison.

Following DTSC’s proposal methodology for filling in Appendix 1 and using the most protective standards, we recreated Appendix 1 (Tables 1-4, below) and filled in each value using OEHHA’s Chemical Database, EPA’s IRIS Chemical Assessments, and HERO’s Note 3 to compare values, and ensure that the most protective values will be used by DTSC. Our review and comparison DTSC’s methodology of these sources and values concerns us because, one, there are instances where an OEHHA value is provided in Appendix 1 because it is to argue that the value is the most protective out of all the other resources, yet IRIS or HERO will provide a more protective standard for that specific analyte. The impression it gives is that DTSC is trying to use a weaker standard for their cleanup efforts, ultimately reducing the quality of any future cleanups. Second, there are values that are left blank in Appendix 1 where it is argued that a value left blank will be filled in by either IRIS or HERO, yet there are analytes that do have an OEHHA value that is more protective than what IRIS or HERO provides, but intentionally not being used.

CBG-04

CBG-05

To prove that the most protective values are not being used for the analytes in the original Appendix 1, we are providing an attachment of the tables we created to compare risk values in our pursuit to ensure the most protective standards are being used. We have taken the initiative to highlight, in our tables, the most protective value that is provided from the three main sources (OEHHA, IRIS, HERO) listed in the proposal. We ask that the Department of Toxic Substances Control use our tables for guidance to ensure that the public’s wellbeing is taken seriously. Any value that is left blank by us are values that do not yet exist for the analyte in OEHHA, IRIS, or HERO. In the final proposal, we expect that any new value provided from an external source be more protective than that of what has been provided. Any use of a weaker standard for any analyte, when a more protective standard exists, will be unacceptable. We are deeply concerned that DTSC is not using the most protective values for the analytes in Appendix 1, whether it is intentional or not. We expect DTSC to protect the general public with the strictest of standards.

CBG-06

### Conclusion

DTSC, it need hardly be said, is a troubled regulatory body. Numerous investigations, legislative expressions of concern, and news media exposures have shown a longstanding dysfunction and failure to protect the public adequately from toxic materials. There has been a disturbing pattern of succumbing to pressures from parties responsible for contamination rather than rigorously regulating them and taking effective action to assure the health of affected communities.

The original proposal from last year—to the extent that it would have required the use of the most protective toxicity criteria—was a step in the right direction. It appears, however, that DTSC has now backed down from that stance, perhaps in response to lobbying from industries that have polluted their sites and neighboring areas, and now proposes in numerous cases to use standards that are less protective than previously promised. This should not be.

CBG-07

Furthermore, DTSC has continued a pattern of not being fully candid about its actions. Here, the statement of reasons for the proposed rule falsely claims that the standards set forth in the rule indeed represent the most protective standards from the primary sources thereof (OEHHA, EPA's IRIS system, or values from DTSC's own HERO), when that is not true. To the contrary, the rule frequently mandates the weaker rather than the stronger standard.

CBG-08

Additionally, this is not disclosed in the proposed rule. DTSC does not provide a comparison of the competing toxicity criteria, thus not making it evident that it is mandating in numerous cases the weaker rather than the more protective standard. We, a public interest organization, had to prepare that comparison, which DTSC should have on its own provided to the public for review during this comment period.

CBG-09

To conclude, we are deeply concerned that DTSC is not using the most protective values for the contaminants listed in the rule. DTSC should – as it incorrectly claimed and as it previously proposed -- protect the general public with the strictest of standards that will protect the health and quality of life for all.

Table 2 - Inhalation Unit Risk (IUR) (ug/m<sup>3</sup>)-1

Analyte	CASRN	OEHHA	EPA IRIS	HERO
Acetaldehyde	75-07-0	2.70E-06	2.20E-06	2.70E-06
Ammonia	7664-41-7	-	-	-
Arsenic	7440-38-2	3.30E-03	4.30E-03	3.30E-03
Arsine	7784-42-1	-	-	-
Benzene	71-43-2	2.90E-05	2.20E-06	2.90E-05
Benzidine	92-87-5	1.40E-01	6.70E-02	1.40E-01
Benzo[a]anthracene	56-55-3	1.10E-04	-	-
Benzo[a]pyrene	50-32-8	1.10E-03	6.00E-04	-
Benzo[b]fluoranthene	205-99-2	1.10E-04	-	-
Benzo[k]fluoranthene	207-08-9	1.10E-04	-	-
Beryllium	7440-41-7	2.40E-03	2.40E-03	2.40E-03
Beryllium Oxide	1304-56-9	2.40E-03	2.40E-03	-
Beryllium Sulfate	13510-49-1	8.60E-01	2.40E-03	8.60E-01
Boron Trifluoride	7637 07 2	-	-	-
Bromoform	75-25-2	-	1.10E-06	1.10E-06
1,3-Butadiene	106-99-0	1.70E-04	3.00E-05	1.70E-04
2-Butoxyethanol	111-76-2	-	-	-
Cadmium	7440-43-9	4.20E-03	1.80E-03	1.80E-03
Carbon tetrachloride	56-23-5	4.20E-05	6.00E-06	4.20E-05
Carbonyl sulfide	463-58-1	-	-	-
Chlordane	57-74-9	3.40E-04	1.00E-04	3.40E-04
Chromium (VI)	18540-29-9	1.50E-01	1.20E-02	1.50E-01
Chrysene	218-01-9	1.10E-05	-	-
dibenz[a,h]anthracene	53-70-3	1.20E-03	-	-
3,3'-Dichlorobenzidine	91-94-1	3.40E-04	-	3.40E-04
1,1-dichloroethene	75-35-4	-	-	-
1,3-Dichloropropene	542-75-6	1.60E-05	4.00E-06	1.60E-05
cis-1,3-Dichloropropene	10061-01-5	1.60E-05	4.00E-06	-
trans-1,3-Dichloropropene	10061-02-6	1.60E-05	4.00E-06	-
1,4-Dioxane	123-91-1	7.70E-06	5.00E-06	7.70E-06
Epichlorohydrin	106-89-8	2.30E-05	1.20E-06	2.30E-05
bis(2-chloroethyl) ether	111-44-4	7.10E-04	3.30E-04	-
Ethylene dibromide	106-93-4	7.10E-05	-	6.00E-04
Formaldehyde	50-00-0	6.00E-06	1.30E-05	1.30E-05
HCH (mixed isomers)	608-73-1	1.10E-03	5.10E-04	1.10E-03
Hexachlorobenzene	118-74-1	5.10E-04	4.60E-04	5.10E-04
Hexachlorobenzeno-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	1.30E+00	3.80E+00
Hydrochloric Acid	7647-01-0	-	-	-
Indeno[1,2,3-cd]pyrene	193-39-5	1.10E-04	-	-
Lead and Compounds	7439-92-1	1.20E-05	-	-

Entire Table is associated with CBG-8

Lead subacetate	1335-32-6	1.10E-05	-	1.10E-05
Manganese (non-diet)	7439-96-5 (non-diet)	-	-	-
Mercuric Chloride	7487-94-7	-	-	-
Mercury	7439-97-6	-	-	-
Methylene Chloride	75-09-2	1.00E-06	1.00E-08	1.00E-06
4,4'-Methylene-bis(2-chloroaniline)	101-14-4	4.30E-04	-	4.30E-04
Methylene diphenyl diisocyanate	101-68-8	-	-	-
Polymeric methylenediphenyl diisocyanate	9016-87-9	-	-	-
Mirex	2385-85-5	5.10E-03	-	5.10E-03
1-Nathylamine	134-32-7	-	-	-
Nickel	7440-02-0	2.60E-04	2.40E-04	2.60E-04
Nickel Hydroxide	12054-48-7	2.60E-04	2.40E-04	2.60E-04
Nickel Oxide	1313-99-1	2.60E-04	2.40E-04	2.60E-04
Nickel refinery dust	Nickel Refinery Dust	2.60E-04	2.40E-04	2.40E-04
Nickel subsulfide	12035-72-2	4.80E-04	4.80E-04	4.80E-04
N-Nitro-di-n-butylamine	924-16-3	3.10E-03	1.60E-03	3.10E-03
Styrene	100-42-5	-	-	-
Tetrachlorethene	127-18-4	6.10E-06	2.60E-07	6.10E-06
Toluene	108-88-3	-	-	-
Toluene 2,4/2,6-diisocyanate	26471-62-5	1.10E-05	-	-
Toluene 2,4-diisocyanate	584-84-9	1.10E-05	-	1.10E-05
Toluene 2,6-diisocyanate	91-08-7	1.10E-05	-	1.10E-05
o-Toluidine	95-53-4	5.10E-05	-	5.10E-05
Toxaphene	8001-35-2	3.40E-04	3.20E-04	3.40E-04
1,1,1-Trichloroethane	71-55-6	-	-	-
2,4,6-Trichlorophenol	88-06-2	2.00E-05	3.10E-06	2.00E-05
Vinyl chloride	75-01-4	7.80E-05	4.40E-06	7.80E-05

#### Most Protective Standard for Analyte

OEHHA=Office of Environmental Health Hazard Assessment-Chemical Data Base

EPA IRIS= Environmental Protection Agency Integrated Risk Information System

HERO= Department of Toxic Substances Control-Office of Human and Ecological Risk Note 3

CASRN=Chemical Abstracts Service

Registry Number

"-" = No Toxicity Value

Table 1 - Oral Slope Factor (CSFo) (mg/kg-d)-1

Analyte	CASRN	OEHA	EPA IRIS	HERO
Acetaldehyde	75-07-0	1.00E-02	-	-
Ammonia	7664-41-7	-	-	-
Arsenic	7440-38-2	1.50E+00	1.50E+00	9.50E+00
Arsine	7784-42-1	-	-	-
Benzene	71-43-2	1.00E-01	-	1.00E-01
Benzidine	92-87-5	5.00E+02	2.30E+02	5.00E+02
Benzo[a]anthracene	56-55-3	1.20E+00	-	-
Benzo[a]pyrene	50-32-8	2.90E+00	1.00E+00	-
Benzo[b]fluoranthene	205-99-2	1.20E+00	-	-
Benzo[k]fluoranthene	207-08-9	1.20E+00	-	-
Beryllium	7440-41-7	-	-	-
Beryllium Oxide	1304-56-9	-	-	-
Beryllium Sulfate	13510-49-1	-	-	-
Boron Trifluoride	7637 07 2	-	-	-
Bromoform	75-25-2	1.10E-02	7.90E-03	7.90E-03
1,3-Butadiene	106-99-0	6.00E-01	-	6.00E-01
2-Butoxyethanol	111-76-2	-	-	-
Cadmium	7440-43-9	-	-	-
Carbon tetrachloride	56-23-5	1.50E-01	7.00E-02	1.50E-01
Carbonyl sulfide	463-58-1	-	-	-
Chlordane	57-74-9	1.30E+00	3.50E-01	1.30E+00
Chromium (VI)	18540-29-9	5.00E-01	-	-
Chrysene	218-01-9	1.20E-01	-	-
dibenz[a,h]anthracene	53-70-3	4.10E+00	-	-
3,3'-Dichlorobenzidine	91-94-1	1.20E+00	4.40E-01	1.20E+00
1,1-dichloroethene	75-35-4	-	-	-
1,3-Dichloropropene	542-75-6	9.10E-02	5.00E-02	9.10E-02
cis-1,3-Dichloropropene	10061-01-5	9.10E-02	5.00E-02	-
trans-1,3-Dichloropropene	10061-02-6	9.10E-02	5.00E-02	-
1,4-Dioxane	123-91-1	2.70E-02	1.10E-01	-
Epichlorohydrin	106-89-8	8.00E-02	9.90E-03	8.00E-02
bis(2-chloroethyl) ether	111-44-4	2.50E+00	1.10E+00	-
Ethylene dibromide	106-93-4	2.50E-01	-	2.00E+00
Formaldehyde	50-00-0	2.10E-02	-	-
HCH (mixed isomers)	608-73-1	4.00E+00	1.80E+00	4.00E+00
Hexachlorobenzene	118-74-1	1.80E+00	1.60E+00	1.80E+00
hexachlorodibenzo-p-dioxin Mixture (2:1 1,2,3,7,8,9- and 1,2,3,6,7,8)	hexachlorodibenzo-p-dioxin mixture	-	6.20E+03	-
Hydrochloric Acid	7647-01-0	-	-	-
Indeno[1,2,3-cd]pyrene	193-39-5	1.20E+00	-	-

Lead and Compounds	7439-92-1	8.50E-03	-	-
Lead subacetate	1335-32-6	3.80E-02	-	3.80E-02
Manganese (non-diet)	7439-96-5 (non-diet)	-	-	-
Mercuric Chloride	7487-94-7	-	2.00E-03	-
Mercury	7439-97-6	-	-	-
Methylene Chloride	75-09-2	1.40E-02	-	1.40E-02
4,4'-Methylene-bis(2-chloroaniline)	101-14-4	1.50E+00	-	1.50E+00
Methylene diphenyl diisocyanate	101-68-8	-	-	-
Polymeric methylenediphenyl diisocyanate	9016-87-9	-	-	-
Mirex	2385-85-5	1.80E+01	-	1.80E+01
1-Nathylamine	134-32-7	1.80E+01	-	-
Nickel	7440-02-0	-	-	-
Nickel Hydroxide	12054-48-7	9.10E-01	-	-
Nickel Oxide	1313-99-1	9.10E-01	-	-
Nickel refinery dust	Nickel Refinery Dust	9.10E-01	-	-
Nickel subsulfide	12035-72-2	1.70E+00	-	1.70E+00
N-Nitro-di-n-butylamine	924-16-3	1.10E-01	5.40E+00	-
Styrene	100-42-5	-	-	-
Tetrachlorethene	127-18-4	5.40E-01	2.10E-03	5.40E-01
Toluene	108-88-3	-	-	-
Toluene 2,4/2,6-diisocyanate	26471-62-5	3.90E-02	-	-
Toluene 2,4-diisocyanate	584-84-9	3.90E-02	-	3.90E-02
Toluene 2,6-diisocyanate	91-08-7	3.90E-02	-	3.90E-02
o-Toluidine	95-53-4	1.80E-01	-	1.80E-01
Toxaphene	8001-35-2	1.20E+00	1.10E+00	-
1,1,1-Trichloroethane	71-55-6	-	-	-
2,4,6-Trichlorophenol	88-06-2	7.00E-02	1.10E-02	7.00E-02
Vinyl chloride	75-01-4	2.70E-01	7.50E-01	2.70E-01

#### Most Protective Standard for Analyte

OEHHA=Office of Environmental Health Hazard Assessment-Chemical Data Base

EPA IRIS= Environmental Protection Agency Integrated Risk Information System

HERO= Department of Toxic Substances Control-Office of Human and Ecological Risk Note 3

CASRN=Chemical Abstracts Service

Registry Number

"-" = No Toxicity Value

Table 3 - Oral Reference Dose (RfDo) (mg/kg-d)

Analyte	CASRN	OEHHA	EPA IRIS	HERO
Acetaldehyde	75-07-0	-	-	-
Ammonia	7664-41-7	-	-	-
Arsenic	7440-38-2	3.50E-06	3.00E-01	3.50E-06
Arsine	7784-42-1	3.50E-06	-	-
Benzene	71-43-2	-	4.00E-03	4.00E-03
Benzidine	92-87-5	-	3.00E-03	3.00E-03
Benzo[a]anthracene	56-55-3	-	-	-
Benzo[a]pyrene	50-32-8	-	3.00E-04	-
Benzo[b]fluoranthene	205-99-2	-	-	-
Benzo[k]fluoranthene	207-08-9	-	-	-
Beryllium	7440-41-7	2.00E-04	2.00E-03	2.00E-04
Beryllium Oxide	1304-56-9	2.00E-04	2.00E-03	-
Beryllium Sulfate	13510-49-1	2.00E-04	2.00E-03	2.00E-04
Boron Trifluoride	7637 07 2	4.00E-02	-	-
Bromoform	75-25-2	-	2.00E-02	2.00E-02
1,3-Butadiene	106-99-0	-	-	-
2-Butoxyethanol	111-76-2	-	1.00E-01	-
Cadmium	7440-43-9	1.10E-05	5.40E-04	6.30E-06
Carbon tetrachloride	56-23-5	-	4.00E-03	4.00E-03
Carbonyl sulfide	463-58-1	-	-	-
Chlordane	57-74-9	3.30E-05	5.00E-04	5.00E-04
Chromium (VI)	18540-29-9	-	3.00E-03	-
Chrysene	218-01-9	2.00E-02	-	-
dibenz[a,h]anthracene	53-70-3	-	-	-
3,3'-Dichlorobenzidine	91-94-1	-	-	-
1,1-dichloroethene	75-35-4	-	5.00E-02	8.00E-04
1,3-Dichloropropene	542-75-6	-	3.00E-02	3.00E-02
cis-1,3-Dichloropropene	10061-01-5	-	-	-
trans-1,3-Dichloropropene	10061-02-6	-	-	-
1,4-Dioxane	123-91-1	-	3.00E-02	-
Epichlorohydrin	106-89-8	-	-	6.00E-03
bis(2-chloroethyl) ether	111-44-4	-	-	-
Ethylene dibromide	106-93-4	-	-	9.00E-03
Formaldehyde	50-00-0	-	2.00E-01	-
HCH (mixed isomers)	608-73-1	-	-	-
Hexachlorobenzene	118-74-1	-	8.00E-04	8.00E-04
Hexachlorobenzene	hexachlorodibenzo-p-dioxin	-	-	-
Hexachlorobenzene	nzo-p-dioxin mixture	-	-	-
Hexachlorobenzene	(2:1 1,2,3,7,8,9- and 1,2,3,6,7,8)	-	-	-
Hydrochloric Acid	7647-01-0	-	-	-
Indeno[1,2,3-cd]pyrene	193-39-5	-	-	-

Lead and Compounds	7439-92-1	1.0 ug/dL*	-	-
Lead subacetate	1335-32-6	-	-	-
Manganese (non-diet)	7439-96-5 (non-diet)	3.00E-02	1.40E-01	2.40E-02
Mercuric Chloride	7487-94-7	-	3.00E-04	1.60E-04
Mercury	7439-97-6	1.60E-02	-	1.60E-04
Methylene Chloride	75-09-2	-	6.00E-03	6.00E-03
4,4'-Methylene-bis(2-chloroaniline)	101-14-4	-	-	2.00E-03
Methylene diphenyl diisocyanate	101-68-8	-	-	-
Polymeric methylenediphenyl diisocyanate	9016-87-9	-	-	-
Mirex	2385-85-5	-	2.00E-04	2.00E-04
1-Nathylamine	134-32-7	-	-	-
Nickel	7440-02-0	1.10E-02	2.00E-02	1.10E-02
Nickel Hydroxide	12054-48-7	1.10E-02	2.00E-02	1.10E-02
Nickel Oxide	1313-99-1	1.10E-02	2.00E-02	1.10E-02
Nickel refinery dust	Nickel Refinery Dust	1.10E-02	2.00E-02	1.10E-02
Nickel subsulfide	12035-72-2	1.10E-02	-	1.10E-02
N-Nitro-di-n-butylamine	924-16-3	-	-	-
Styrene	100-42-5	-	2.00E-01	-
Tetrachlorethene	127-18-4	-	6.00E-03	6.00E-03
Toluene	108-88-3	-	8.00E-02	8.00E-02
Toluene 2,4/2,6-diisocyanate	26471-62-5	-	-	-
Toluene 2,4-diisocyanate	584-84-9	-	-	-
Toluene 2,6-diisocyanate	91-08-7	-	-	-
o-Toluidine	95-53-4	-	-	-
Toxaphene	8001-35-2	-	-	-
1,1,1-Trichloroethane	71-55-6	-	2.00E+00	2.00E+00
2,4,6-Trichlorophenol	88-06-2	-	-	1.00E-03
Vinyl chloride	75-01-4	-	3.00E-03	3.00E-03

\*=The RfD for Lead is expressed as ug/dL (microgram per deciliter)

"-" = No Toxicity Value

#### Most Protective Standard for Analyte

OEHHA=Office of Environmental Health Hazard Assessment-Chemical Data Base

EPA IRIS= Environmental Protection Agency Integrated Risk Information System

HERO= Department of Toxic Substances Control-Office of Human and Ecological Risk Note 3

CASRN=Chemical Abstracts Service

Registry Number

Table 4 - Reference Exposure Level (REL) or Reference Concentration (RfC) (ug/m<sup>3</sup>)

Analyte	CASRN	OEHHA	EPA IRIS	HERO
Acetaldehyde	75-07-0	1.40E+02	9.00E+00	9.00E+00
Ammonia	7664-41-7	2.00E+02	5.00E+02	2.00E+02
Arsenic	7440-38-2	1.50E-02	-	1.50E-02
Arsine	7784-42-1	1.50E-02	5.00E-02	1.50E-02
Benzene	71-43-2	3.00E+00	3.00E+00	3.00E+00
Benzidine	92-87-5	-	-	-
Benzo[a]anthracene	56-55-3	-	-	-
Benzo[a]pyrene	50-32-8	-	2.00E-03	-
Benzo[b]fluoranthene	205-99-2	-	-	-
Benzo[k]fluoranthene	207-08-9	-	-	-
Beryllium	7440-41-7	7.00E-03	2.00E-02	7.00E-03
Beryllium Oxide	1304-56-9	7.00E-03	2.00E-02	-
Beryllium Sulfate	13510-49-1	7.00E-03	2.00E-02	7.00E-03
Boron Trifluoride	7637 07 2	-	-	7.00E-01
Bromoform	75-25-2	-	-	8.00E+01
1,3-Butadiene	106-99-0	2.00E+00	3.00E+00	2.00E+00
2-Butoxyethanol	111-76-2	8.20E+01	1.60E+03	8.20E+01
Cadmium	7440-43-9	2.00E-02	-	1.00E-02
Carbon tetrachloride	56-23-5	4.00E+01	1.00E+01	4.00E+01
Carbonyl sulfide	463-58-1	1.00E+01	-	1.00E+01
Chlordane	57-74-9	-	4.00E-01	7.00E-01
Chromium (VI)	18540-29-9	2.00E-01	8.00E-03	1.00E-01
Chrysene	218-01-9	-	-	-
dibenz[a,h]anthracene	53-70-3	-	-	-
3,3'-Dichlorobenzidine	91-94-1	-	-	-
1,1-dichloroethene	75-35-4	7.00E+01	2.00E+02	7.00E+01
1,3-Dichloropropene	542-75-6	-	2.00E+01	2.00E+01
cis-1,3-Dichloropropene	10061-01-5	-	-	-
trans-1,3-Dichloropropene	10061-02-6	-	-	-
1,4-Dioxane	123-91-1	3.00E+03	3.00E+01	3.00E+01
Epichlorohydrin	106-89-8	3.00E+00	3.00E+00	1.00E+00
bis(2-chloroethyl) ether	111-44-4	-	-	-
Ethylene dibromide	106-93-4	8.00E-01	-	8.00E-01
Formaldehyde	50-00-0	9.00E+00	-	9.00E+00
HCH (mixed isomers)	608-73-1	-	-	-
Hexachlorobenzene	118-74-1	-	-	3.20E+00
Hexachlorobenzene	hexachlorodibe			
Hexachlorobenzene	nzo-p-dioxin			
Hexachlorobenzene	mixture	-	-	-
Hexachlorobenzene	(2:1 1,2,3,7,8,9- and 1,2,3,6,7,8)			
Hydrochloric Acid	7647-01-0	9.00E+00	2.00E+01	9.00E+00
Indeno[1,2,3-cd]pyrene	193-39-5	-	-	-

Lead and Compounds	7439-92-1	-	-	-
Lead subacetate	1335-32-6	-	-	-
Manganese (non-diet)	7439-96-5 (non-diet)	9.00E-02	5.00E-01	9.00E-02
Mercuric Chloride	7487-94-7	3.00E-02	-	3.00E-02
Mercury	7439-97-6	3.00E-02	3.00E-01	3.00E-02
Methylene Chloride	75-09-2	4.00E+02	6.00E+02	6.00E+02
4,4'-Methylene-bis(2-chloroaniline)	101-14-4	-	-	-
Methylene diphenyl diisocyanate	101-68-8	8.00E-02	6.00E-01	8.00E-02
Polymeric methylenediphenyl diisocyanate	9016-87-9	8.00E-02	6.00E-01	8.00E-02
Mirex	2385-85-5	-	-	8.00E-01
1-Nathylamine	134-32-7	-	-	-
Nickel	7440-02-0	1.40E-02	-	1.40E-02
Nickel Hydroxide	12054-48-7	1.40E-02	-	1.40E-02
Nickel Oxide	1313-99-1	2.00E-02	-	2.00E-02
Nickel refinery dust	Nickel Refinery Dust	1.40E-02	-	1.40E-02
Nickel subsulfide	12035-72-2	1.40E-02	-	1.40E-02
N-Nitro-di-n-butylamine	924-16-3	-	-	-
Styrene	100-42-5	9.00E+02	1.00E+03	9.00E+02
Tetrachlorethene	127-18-4	3.50E+01	4.00E+01	4.00E+01
Toluene	108-88-3	3.00E+02	5.00E+03	3.00E+02
Toluene 2,4/2,6-diisocyanate	26471-62-5	8.00E-03	7.00E-02	-
Toluene 2,4-diisocyanate	584-84-9	8.00E-03	7.00E-02	8.00E-03
Toluene 2,6-diisocyanate	91-08-7	8.00E-03	7.00E-02	8.00E-03
o-Toluidine	95-53-4	-	-	-
Toxaphene	8001-35-2	-	-	-
1,1,1-Trichloroethane	71-55-6	1.00E+03	5.00E+03	1.00E+03
2,4,6-Trichlorophenol	88-06-2	-	-	-
Vinyl chloride	75-01-4	-	1.00E+02	1.00E+02

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"-" = No Toxicity Value



## California Council for Environmental and Economic Balance

101 Mission Street, Suite 1440, San Francisco, California 94105  
415-512-7890 phone, 415-512-7897 fax, [www.cceeb.org](http://www.cceeb.org)

September 20, 2017

Mr. Kevin Depies  
Department of Toxic Substances Control  
8800 Cal Center Drive  
Sacramento, California 95826  
*Electronic Submission via: [ToxCriteriaRule@dtsc.ca.gov](mailto:ToxCriteriaRule@dtsc.ca.gov)*

### **Re: Comments Regarding the DTSC Toxicity Criteria Rule**

Dear Mr. Depies:

On behalf of the members of the California Council for Environmental and Economic Balance (CCEEB), we appreciate the opportunity to offer the following comments regarding the Department of Toxic Substances Control's (DTSC) Toxicity Criteria for Human Health Risk Assessments and Health Based Decision Making regulation ("proposed regulation"). Additionally, we greatly appreciate the time staff provided to meet with our members and discuss the proposed regulation in greater detail.

CCEEB is a coalition of business, labor, and public leaders that works together to advance strategies to achieve a sound economy and a healthy environment. Founded in 1973, CCEEB is a non-profit and non-partisan organization.

As you know, CCEEB participated in the December 2016 workshop and submitted comments in January conveying concerns regarding the lack of clarity and intent associated with the development of this regulation. And while we recognize and are appreciative of the changes incorporated from the earlier January version, CCEEB continues to have concerns with the proposed regulation. This letter serves to outline those concerns and the attachment offers proposed changes to the regulatory text to help address the concerns raised.

### **Remediation Goal Definition**

During the workshop and as part of our conversations with you, we raised the concern that the proposed regulation's definition of "remediation goal" under Section 69020(c)(5)(ii) provides for "site-specific" consideration and yet the proposed regulation fails to provide flexibility in this context. While we appreciate DTSC's explanation that site specific considerations are a separate step in the process of establishing clean up goals that are outside the scope of this regulation, we remain concerned that removing the flexibility associated with choosing the toxicity value in and of itself fails to account for site specific considerations as it may require a value be used that is more stringent than necessary for the site specific use going forward. We remain concerned that a lack

CCEEB-01

of flexibility even in the determination of the toxicity value relative to site specific decision making can result in unintended consequences related to duration of remediation processes, property values, undermining the Brownfields program, and more. CCEEB-01 (cont.)

Additionally, we recommend the definition of “remediation goal” be revised to also account for land use consideration. Specifically, CCEEB recommends the following revision to the definition: CCEEB-02

(5) “Remediation Goal” is a contaminant concentration that is: (i) media-specific (e.g., for the air, groundwater, surface water, or soil affected by a release); (ii) site-specific; (iii) land use-specific; (iv) protective of human health and the environment; and (v) serves as a final cleanup goal for the response or corrective action.

### Peer Review Definition

CCEEB-03 — We request a definition of the term “peer-review” and that DTSC make transparent their systematic review principles that the agency incorporates into a determination for any “best available” toxicity value for use. This process should be transparent to the regulated community, citizens and relevant stakeholders.

CCEEB agrees that toxicity factors should be based on best available sound science consistent with Health & Safety Code Section 116365(c)(1). Our concern is that DTSC has yet to make public the documented process by which science and journal publications are reviewed. Several other state governments widely recognize that a publicly vetted process is a necessary component of transparently concluding a study represents “best available science.” A rubric and guidance document defining the transparent systematic review is absent from the rule proposed. We have outstanding ambiguity regarding how DTSC ensures the “peer-review” source is credible and deemed to be “best available” science. How does DTSC affirm that the study is well-designed and the findings and conclusions are appropriate? How does DTSC assure that sources of potential author bias are clearly independent of the publication’s conclusions? CCEEB-04

To address these concerns regarding ambiguity, CCEEB recommends the following:

“Peer Review” means generally accepted and evidence-based research that is not refuted by subsequent experiment or evidence. CCEEB-03 (cont.)

Notably, this proposed definition is consistent with 3 CCR 1301(r) that similarly defines “credible scientific research” to mean “research published in a peer-reviewed publication and not refuted by subsequent experiment or evidence.”

### Variance

In our written comments from January, CCEEB requested the inclusion of a variance procedures so as to allow the Department flexibility in determining the most appropriate toxicity criteria based on site specific considerations. We continue to believe a variance should be incorporated in the proposed regulation. CCEEB-05

## Applicable Toxicity Criteria

While we agree that the toxicity factors should be based on best available science consistent with Health & Safety Code Section 116365(c)(1), CCEEB is concerned that DTSC has yet to make public the process by which science or journal publications are reviewed. How does DSC ensure the “sound science” source is credible, sound, the study is well-designed and the findings and/or conclusions are appropriate?

CCEEB-06

Further, some values under Tier 1, as formalized by the Office of Environmental Health Hazard Assessment’s (OEHHA), are more stringent than federal values and are not necessarily based on the most recent science as is the case with some of the IRIS values.

CCEEB-07

These points notwithstanding, CCEEB recommends the following revisions to Section 69021 to be clear that the unit risk factors and sources are peer reviewed and evidence based:

- (a) OEHHA’s peer reviewed, evidence based unit risk factors, oral slope factors, reference exposure levels (RELs), and reference dose(s) (RfDs), as listed in Appendix I to this Chapter, shall be used for the COPCs which are listed in this Appendix. If Appendix I does not list toxicity criteria for a specific COPC then the toxicity criteria listed under section 69021, subdivision (b) shall be used.
- (b) The peer reviewed, evidence based unit risk factors, oral slope factors, reference dose(s) (RfDs), and reference concentrations (RfCs), identified in U.S. EPA’s Integrated Risk Information System (IRIS) shall be used where Section 69021, subdivision (a) above does not specific toxicity criteria for a particular COPC. If IRIS does not list toxicity criteria for a specific COPC then the toxicity criteria listed under section 69021, subdivision (c) shall be used.
- (c) Toxicity criteria from another peer reviewed, evidence based source, that applies the best available science and is health-based, may be used in human health risk assessments upon approval by the Supervising Toxicologist, of the Department’s Human and Ecological Risk Office, or his or her designee, when neither subdivision (a) nor subdivision (b) above specifies toxicity criteria for the particular COPC. Other peer reviewed, evidence based sources include, but are not limited to: OEHHA toxicity criteria that are not listed in Appendix I (e.g., those toxicity criteria used in U.S. EPA’s Regional Screening Levels), U.S. EPA Provision Peer Reviewed Toxicity Values (PPRTVs) (excluding TPH PPRTVs), Agency for Toxic Substances and Disease Registry Minimal Risk Levels, PPRTV Appendix Screening Toxicity Values, and U.S. EPA Superfund Health Effects Assessment Summary Table values. Any selected toxicity criteria or value used under this subdivision shall be consistent with Health and Safety Code section 2536.1.5, subdivision (c).

CCEEB-08

## Screening Levels and Remediation Goals

CCEEB also recommends the following revisions to Section 69022(c) to incorporate additional relevant statutory references, as follows:

CCEEB-09

(b) *When based on human health risk or non-cancer hazard, screening levels for individual COPCs shall be set to:*

- (1) *An incremental excess lifetime cancer risk to an individual of  $1 \times 10^{-4}$  to  $1 \times 10^{-6}$ , and as outlined in the NCP.*
- (2) *A hazard quotient of 1.*

CCEEB-09

(c) *All human health risk-based remediation goals for response actions conducted under Health and Safety Code, Division 20, Chapter 5, 6.5, 6.8, and 6.82 shall comply with Health and Safety Code section 25356.1.5(a)(1) and (d).*

CCEEB-10

As suggested in our January letter and discussed at length during our meetings with staff, CCEEB continues to believe maintaining DTSC's flexibility in determining the best toxicity criteria value associated with site specific considerations is important. Not only will such flexibility help reduce the unnecessary generation, disposal and potential exposure associated with higher levels of contaminated soils in need of excavation, transport and disposal, it could also help avoid significant delays in remediation projects, reduce the long-term stigma associated with delays in cleaning up brownfield and remediate properties, and minimize negative property value impacts.

CCEEB-11

Thank you for the opportunity to comment and for your consideration of our concerns and recommended revisions. CCEEB looks forward to working with DTSC to develop Toxicity Criteria that are workable, consistently applied, and protective of human health. Should you have questions, please contact CCEEB's Water, Chemistry and Waste Project Manager Dawn Koepke with McHugh, Koepke & Associates at (916) 930-1993. Thank you.

Sincerely,



Gerald D. Secundy  
CCEEB President

cc: Mohsen Nazemi, Deputy Director, Site Mitigation & Brownfields Reuse Program, DTSC  
CCEEB WCW Project Members  
The Gualco Group, Inc.

**From:** Marisa Hull  
**To:** [toxcrieriarule](#)  
**Subject:** ATTENTION: Submittal of Comments on the Proposed Toxicity Criteria Rule  
**Date:** Wednesday, September 20, 2017 4:56:50 PM  
**Attachments:** [Coalition Letter DTSC Toxicity Criteria 09 20 17 - FINAL.PDF](#)  
**Importance:** High

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Good afternoon Mr. Depies,

On behalf of Dorothy Rothrock, President, California Manufacturers and Technology Association, I am submitting to you our coalition comments letter in response to the Department of Toxic Substances Control's (DTSC) Proposed Toxicity Criteria Rule. Feel free to contact me if you have any questions regarding the attached.

Sincerely,

Marisa Melendez-Hull

**Marisa Melendez-Hull**

Legislative Assistant

**DIRECT:** (916) 498-3321

**FAX:** (916) 441-5449

**EMAIL:** [mhull@cmta.net](mailto:mhull@cmta.net)

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September 20, 2017

Department of Toxic Substances Control  
1001 I Street  
P.O. Box 806  
Sacramento, CA 95812-0806  
**Attn: Kevin Depies**

**Subject: Proposed Regulation on Toxicity Criteria for Human Health Risk Assessment**

Dear Mr. Depies:

The undersigned organizations appreciate this opportunity to comment on the Department of Toxic Substances Control's (hereafter "the Department") proposed regulations that would designate toxicity criteria for human health risk assessments supporting remedial action decisions at contaminated properties under the Department's jurisdiction.

We acknowledge at the outset that the Department has made some changes to the informal proposal in response to stakeholder comments. We note removal of language requiring that screening levels must consider cumulative risk or hazard index across all chemicals and pathways. As we indicated in our January 31, 2017 comments on the informal proposal, it is not possible to calculate screening values that consider the cumulative effect of all chemicals across all pathways, and this approach would alter established risk assessment policy. Accordingly, the new language at Section 69022 appropriately limits the scope of screening levels to individual contaminants.

One issue of particular concern acknowledged in the Initial Statement of Reasons (ISOR) is the potential "loss of discretion to choose remediation goals within the risk management range of  $10^{-4}$  and  $10^{-6}$ " (ISOR, page 23). The ISOR also states that "this rule does not replace the [Superfund National Contingency Plan] in any way." Despite these assurances and a statutory reference to compliance with the NCP (Section 69022(c)), removal of prior language establishing benchmarks for "points of departure" at the low end of the NCP risk range, coupled with the definition of "Remediation Goal" as "a *final* cleanup goal for the response or corrective action" (Section 69020(c)(5), emphasis added), only serves to amplify our prior concern that this rulemaking would anchor cleanup levels at the low end of the NCP risk range (i.e., excess cancer risk of one in one million or  $1 \times 10^{-6}$ ).

CMTA-01

The ISOR states that the primary purpose of the proposed regulations is to qualify certain toxicity criteria developed by the Cal-EPA Office of Environmental Health Hazard Assessment (OEHHA) as Applicable or Relevant and Appropriate Requirements (ARARs) so that the U.S. Department of Defense will be compelled to use them at federal Superfund sites in California. However, the impacts of the proposed regulation could be much more widespread, affecting all sites subject to Department jurisdiction and creating a prescriptive program that itself will require more Department staff resources to manage, that will remove the discretion of risk management professionals to consider the best

CMTA-02

CMTA-03

CMTA-03 — [available science and site-specific circumstances, and that will drive up costs to the regulated community and state taxpayers by saddling the Department with additional costs at orphan sites. — CMTA-04

The Department also claims that the proposed regulation is necessary because of California’s unique statutory requirements and demographic constitution. However, requiring application of default human health risk-based criteria at all sites state-wide runs contrary to the purported goal of tailoring remedies to site-specific circumstances, including but not limited to potential variability among sensitive populations. — CMTA-05

A more in-depth analysis of the proposed regulatory language and supporting documentation only serves to reinforce the conclusion that the Department’s proposed remedy is disproportionate to the scope of the problem it seeks to solve. For these reasons, and those articulated in the following comments and in our January 31, 2017 comments on the informal draft, we request that the Department abandon this proposal and instead resume negotiations with the Department of Defense to establish appropriate toxicity criteria for risk assessments at federally owned and operated Superfund sites. — CMTA-06

Thank you for considering our comments. If you have any questions, please do not hesitate to contact Dorothy Rothrock, President, California Manufacturers and Technology Association at [drothrock@cmta.net](mailto:drothrock@cmta.net) or 916-498-3319.

Sincerely,

- American Chemistry Council
- Battery Council International
- California Building Industry Association
- California Business Properties Association
- California Chamber of Commerce
- California Construction and Industrial Materials Association
- California Independent Oil Marketers Association
- California Manufacturers & Technology Association
- Chemical Industry Council of California
- Metal Finishing Association of Southern California
- Metal Finishing Association of Northern California
- National Federation of Independent Business
- Western Independent Refiners Association
- National Shooting Sports Foundation
- Sporting Arms and Ammunition Manufacturers’ Institute
- West Coast Lumber and Building Material Association
- Western States Petroleum Association

cc: Barbara Lee, Director  
Mohsen Nazemi, Deputy Director, Brownfields and Site Remediation  
Matthew Rodriquez, Secretary, Cal-EPA  
Kim Craig, Governor’s Office

# Detailed Comments on the Proposed Regulation on Toxicity Criteria for Human Health Risk Assessment

## Scope and Justification

The ISOR explains that the proposed regulations are needed in connection with disputes with the US Air Force regarding the toxicity criteria that should be used for perchloroethylene (PCE) at the Edwards Air Force Base Superfund site (ISOR page 3, page 20). The Department's stated goal is to qualify OEHHA toxicity criteria as Applicable or Relevant and Appropriate Requirements (ARARs) to compel their use at federally owned and operated Superfund sites (ISOR page 9). Based on the Department's supporting documentation, the proposed regulations, which would apply to all hazardous material release sites under the Department's jurisdiction, appear to be an over-reaction to a breakdown in negotiations with the federal government at a single site.

CMTA-06  
(cont.)

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

CMTA-07

## Effect of the Proposed Regulations

The regulations that currently govern the adoption of final remediation goals are the federal regulations contained in the National Contingency Plan (NCP). 40 CFR 300.430. Under the NCP, the lead agency initiates identification of potential federal and state ARARs during the scoping of the Remedial Investigation (RI). 40 CFR 300.430(b)(9). As the RI proceeds, the lead and support agencies may identify additional ARARs and other criteria or guidance to be considered (TBC) for a particular release. 40 CFR 300.430(g)(3). During the Feasibility Study (FS), remedial action objectives and preliminary remediation goals (PRGs) are developed. 40 CFR 300.430(e)(2)(i). PRGs are based on ARARs and other information, including various toxicity values. *Id.* The lead agency has discretion as to which toxicity values to use in establishing PRGs, as described in U.S. Environmental Protection Agency (EPA) guidance documents. *See*, Risk Assessment Guidance Part B. For known or suspected carcinogens, the  $1 \times 10^{-6}$  risk level is used as a point-of-departure for determining PRGs when ARARs are not available. 40 CFR 300.430(e)(2)(i)(A)(2).

Text here  
feeds  
CMTA-08,  
09, 10  
below

Later in the FS process, remedial alternatives are assessed to determine whether they attain ARARs. 40 CFR 300.430(e)(9)(iii)(B). Remedial alternatives that do not satisfy ARARs are not eligible for selection as the final remedy. 55 Fed. Reg. 8724 (Mar. 8, 1990). For contaminants and/or environmental media where ARARs do not exist, the  $10^{-6}$  point-of-departure for PRGs represents a preference for setting cleanup levels at the more protective end of the risk range. However, final remediation goals may be set at a risk level within the  $10^{-4}$  to  $10^{-6}$  risk range based on consideration of several factors. The final

Feeds  
CMTA-08,  
09, 10  
below

selection of the appropriate risk level—and the final remediation goals—is determined when the final remedy is selected based on the balancing of the remedy selection criteria in the NCP.

Under the proposed regulations, three things would change: (1) the discretion of the lead agency as to which toxicity values to use in developing PRGs would be largely eliminated; (2) the remediation goals derived from toxicity values would be ARARs; and (3) the remediation goals derived from toxicity values would appear to be set at a  $10^{-6}$  risk level instead of in the  $10^{-4}$  to  $10^{-6}$  risk range.

CMTA-08,  
09, and  
10

First, under the proposed regulations, the toxicity value chosen to establish a remediation goal must be an OEHHA-derived toxicity value listed in Appendix I, unless Appendix I does not contain a value for the particular contaminant and/or environmental media. If that is the case, the toxicity value chosen must be a unit risk factor, oral slope factor, reference dose or reference concentration identified in EPA’s IRIS system, unless IRIS does not contain a value for the particular contaminant and/or media. Only if a toxicity value does not exist in Appendix I or IRIS does limited discretion come into play. This is different from existing practice.

CMTA-08

Second, one of the stated purposes of the proposed regulations is to qualify remediation goals derived from toxicity values as ARARs. Such remediation goals are not ARARs under the current regulatory scheme. As a result, in the remedy selection process, remedial alternatives that do not satisfy all of the remediation goals derived from toxicity values would not be eligible for selection as a final remedy. That approach is different from existing practice.

CMTA-09

Third, under the proposed regulations, screening levels and remediation goals are required to use the toxicity values described above (i.e., toxicity values from Appendix I if they exist, then from IRIS, then from other sources). The proposed regulations provide that screening levels shall be set to an incremental excess cancer risk of  $1 \times 10^{-6}$ . “Remediation goals” are defined as concentrations that serve as *final* cleanup goals for the response or corrective action. In addition, language from the prior proposal that toxicity criteria would be used as a point-of-departure has been deleted. Finally, the proposed regulations do not provide that final remediation goals may be set in the  $10^{-4}$  to  $10^{-6}$  risk range based on the balancing of remedy selection criteria. Again, this appears to be different from existing practice.

CMTA-10

The proposed regulations also lack clarity. Under the NCP, PRGs are developed for contaminants and/or media for which ARARs do not exist and final remediation goals for these contaminants are developed in connection with final remedy selection. The proposed regulations do not use the terms “preliminary remediation goals” or “final remediation goals” and introduce a term, “screening level” that is not used in the NCP. As a result, the manner in which the proposed regulations would interface with the NCP for purposes of selection of final remediation goals is unclear.

CMTA-11

### Toxicity Criteria Selection Policy

The Department asserts that one of the benefits of the proposed regulation is it “ensures that toxicity criteria used in California are of high scientific quality and credibility and apply the best available

CMTA-12

science” (ISOR page 22), but the Department’s inconsistent treatment of OEHHA values in Appendix 1 and the design of the proposed selection criteria do not support this claim.

CMTA-12

OEHHA values for certain chemicals are omitted from Appendix 1. Examples include, but are not limited to, cancer potency values for **formaldehyde** (OEHHA, 1992) and **trichloroethylene** (OEHHA, 2009), and non-cancer health hazard values for **hexavalent chromium** (OEHHA 2001). These omissions are at odds with the Department’s statement that “OEHHA toxicity criteria are better suited and more inclusive of California’s diverse demographic, and more protective than federal law” (ISOR, page 10). With the exception of trichloroethylene (TCE), they would also result in default application of EPA IRIS values that pre-date the corresponding OEHHA values for the subject chemicals. For each of these chemicals, the IRIS values result in more stringent toxicity values. We are concerned that the Department is not applying consistent criteria in determining which toxicity values should be used, but is instead selecting the most stringent values regardless of the scientific merits of those values. Appendix 1 also includes OEHHA values that predate corresponding IRIS values, in some cases by decades, or values that are clearly not based on the best available science. For example, the 1993 OEHHA-derived cancer potency value for **benzo[a]pyrene** is listed in Appendix 1 and would supersede the corresponding EPA IRIS value, updated in 2017. Department staff stated during the August 28 workshop that they use/will use the updated IRIS value for B[a]P<sup>1</sup>, yet inclusion of the outdated OEHHA value in Appendix 1 would eliminate their discretion to do so. Appendix 1 lists OEHHA’s cancer potency values for **1,3 butadiene**, adopted in 1992. EPA IRIS developed a cancer potency value for 1,3 butadiene in 2002 based on data that was not available to OEHHA, including a 2-year mouse inhalation study published by NTP in 1993.

CMTA-12.1, 12.2, 12.3

For **1,4-dioxane**, DTSC recommends using an OEHHA-calculated toxicity value for the inhalation unit risk (IUR) value and an IRIS-calculated toxicity value for the reference concentration (RfC). In this case, the IRIS assessment for 1,4-dioxane is based on a more recent data analysis. However, the OEHHA value is maintained for the IUR. Again, we are concerned that the Department is selecting the most stringent values regardless of the scientific merits of those values.

CMTA-12.4

Appendix 1 characterizes the incremental value of 1 microgram per decilitre (ug/dL) as a toxicity value for **lead**. That is not correct. Instead, that value represents a benchmark incremental change in blood lead concentration. The Department’s proposed use of this value, combined with OEHHA’s decision that the soil lead screening concentration should correspond to a 90<sup>th</sup> percentile estimate of increase in blood lead of 1 ug/dL (OEHHA 2009), would severely restrict the use of site specific factors that should bear upon a risk assessment and the establishment of clean up goals. Such an approach is improper and inconsistent with federal and California law.

CMTA-12.5

Current Department guidance for human health risk assessment<sup>2</sup> states:

**For the majority of the approximately 800 listed RSL chemicals, HERO endorses the values listed in the USEPA RSL tables. However, some values listed in the USEPA RSL tables differ significantly (greater than three-fold less protective) from values calculated using Cal-EPA toxicity criteria and**

CMTA-12.6

<sup>1</sup> Human and Ecological Risk Office Note 3, updated April, 2017.

<sup>2</sup> Id.

risk assessment procedures. DTSC-SLs for soil and tap water are identified when the value is at least three-fold more stringent than the corresponding USEPA RSL, while an air DTSC-SL is identified when the DTSC-SL value is more stringent than the corresponding USEPA RSL by any degree.

This guidance indicates that the Department applies varying criteria based on the media of concern. For soil and water, the Department uses USEPA RSLs where there is less than a three-fold difference relative to Cal-EPA values. For air, the guidance suggests the Department uses the lowest available value.

More importantly, all of the above examples suggest a policy of always requiring the lowest available values, regardless of whether those values are based on the best available science or consider site-specific circumstances that may warrant a different approach.

CMTA-12.6

### Toxicity Criteria Selection Policy Exceptions

Section 69021 (c) specifies that in the absence of *both* (OEHHA) criteria from Appendix 1 *and* IRIS criteria for a particular chemical, toxicity criteria may be obtained from “another source, that applies the best available science and is health-based” upon approval by the Department’s Human and Ecological Risk Office (HERO) on a site-specific basis. Department staff stated during the August 28 workshop that the RP “is always welcome to propose what it thinks is the right number”, then negotiate a final value with DTSC. It is not clear how this process would lead to selection of values that would qualify as ARARs, given the ad-hoc nature of the process and the fact that the values themselves would not be codified in the regulations.

CMTA-13

Department staff stated during the August 28 workshop that they are proposing to anchor the chemical hazard assessment component of the risk-based remedy selection process at the low end of the NCP risk range, but that exposure variables can be adjusted to reflect site-specific conditions. Risk management professionals should be permitted discretion to consider all relevant site-specific factors in health risk assessments, not just those related to chemical exposure. The ISOR actually offers a compelling argument in support of preserving such discretion. It identifies metal alloys as an exception to the use of default toxicity criteria where those criteria were developed for elemental metals, based on the recognition that the alloy may exhibit different toxicity (e.g., reduced bioavailability) than the elemental metals (ISOR, page 15). This exception underscores the importance of preserving Department discretion in selecting toxicity criteria to account for potentially significant differences in health risk between the baseline assumptions embedded in default toxicity criteria and the actual conditions at a given site.

CMTA-14

### Consistency with Federal Law

Section 69022(c) of the proposed regulations requires the Department to comply with federal law and guidance in establishing human health risk-based remediation goals under the Health and Safety Code. The staff workshop presentation at slide 6 indicates that the federal hierarchy for toxicity criteria selection is discretionary, with the notable exception that it specifically requires consideration of best available science. It is unclear how the proposed selection hierarchy complies with federal law and guidance.

CMTA-15

## Scientific Integrity of Toxicity Criteria

Despite the Department's assertions to the contrary, OEHHA toxicity values are not subject to the same level of external scientific peer review and public input as federal values developed under the EPA IRIS program. The ISOR states that the OEHHA process for developing toxicity values includes a "transparent, scientifically supported and high quality peer-review process that solicits, incorporates and addresses public and professional comments" (ISOR, page 9). However, the Department fails to describe the actual processes used to develop the OEHHA values. In fact, the process and level of rigor varies significantly based on the source program. For example, inhalation cancer potency factors are subject to review by a standing panel of subject matter experts covering a broad range of scientific disciplines (the Scientific Review Panel on Toxic Air Contaminants), while oral cancer potency factors developed for Public Health Goals (PHGs) are subject to the comparatively ad-hoc peer review process established at Health and Safety Code section 57004. Department staff also acknowledged during the August 28 workshop that some OEHHA values are reviewed individually, while others are reviewed in batches, such as the cancer potency factors included in OEHHA's technical support document for the Air Toxics Hot Spots program (2009)<sup>3</sup>.

Regardless of the source program, the OEHHA values are not established through a formal rulemaking process. By contrast, most ARARs were promulgated one at a time pursuant to notice and comment rulemaking (e.g., Maximum Contaminant Levels). The broad brush incorporation by reference approach in the proposed regulations does not provide the same level of analytical rigor, external scientific peer review or meaningful stakeholder input as a one-at-a-time regulatory standard setting process. Moreover, there is no indication in the ISOR that the individual Appendix 1 values have been independently peer reviewed and determined to be superior to IRIS values based on best available science and applicable state statutory requirements.

### PCE Example

A review of the development of toxicity values for tetrachloroethylene (PCE) illustrates that the OEHHA process is not as rigorous as IRIS. Table 1 presents the steps used by OEHHA and the EPA IRIS program to develop the published toxicity values for PCE. As demonstrated in Table 1, the EPA IRIS process included an additional outside peer review by the National Academy of Sciences (NAS) to evaluate the adequacy of the assessment, the data and methods used to develop toxicity values, whether the key studies are of requisite quality, reliability, and relevance to support the derivation of toxicity values, and whether the uncertainties in EPA's risk assessment were adequately described, and where possible, quantified. In response to the NAS review, EPA utilized a harmonized physiologically-based pharmacokinetic (PBPK) model and then conducted focused peer reviews on the application of this model in the final document.

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<sup>3</sup> Appendix A lookup table containing unit risk and cancer potency values updated in 2011. See: <https://oehha.ca.gov/media/downloads/cnr/appendixa.pdf>.

Table 1. Tetrachloroethylene Review Process for OEHHA and IRIS.

OEHHA	IRIS
<p>15 Feb 2016 – Public Review Draft -45 day public comment period. Panel members include: Michael Kleinman, Ph. D., Air Pollution Health Effects Laboratory, U.C. Irvine; S. Katherine Hammond, Ph. D., U.C. Berkeley School of Public Health; Cort Anastasio, Ph. D., U.C. Davis; Jesus Araujo, M.D., Ph.D., U.C. Los Angeles; Alan Buckpitt, Ph.D., U.C. Davis, and Stanton Glantz, Ph. D., U.C. San Francisco.</p>	<p>Jan 2004 – Charge to the Tetrachloroethylene Neurotoxicity Expert Panel. Members include Kent Anger, Oregon Health and Science University; Rosmarie Bowler, San Francisco State University; Diana Echeverria, Battelle Center for Public Health Research and Evaluation; Fabriziomaria Gobba, University di Modena e Reggio, Italy; William Merigan, University of Rochester School of Medicine and Dentistry.</p>
<p>8 and 11 Mar 2016 – Public Workshops in Southern and Northern California to Scientific Review Panel.</p>	<p>July 2008 – 90-day public comment period on draft EPA Toxicological Review of Tetrachloroethylene. EPA received 20 comments from the public on the draft report.</p>
<p>End of Mar 2016 – OEHHA receives a total of 44 individual and compound comments including comments from California Chamber of Commerce, Center for Public Environmental Oversight, Halogenated Solvents Industry Alliance, and US Department of the Navy</p>	<p>August 2008 – EPA listening session to obtain public comment on the draft EPA Toxicological Review of Tetrachloroethylene</p>
<p>May 2016 - Responses to Public Comment on the Draft Inhalation Unit Risk Factor for Perchloroethylene The major issues were grouped into the following categories: (1) Not following USEPA methods; (2) PBPK inhalation model; (3) Use of the NTP study data; (4) Use of the rat MCL data; (5) Use of total metabolized dose; (6) Use of multiple tumor sites; (7) Use of geometric mean for final URF; (8) Need for more uncertainty analysis.</p>	<p>Oct 2008 –National Academy of Sciences (NAS), National Research Council (NRC) initiates an external peer review of the draft Toxicological Review of Tetrachloroethylene. Peer review panel tasked with evaluating: (1) the adequacy of the EPA assessment, the data and methods used for deriving the noncancer values for inhalation and oral exposures and the oral and inhalation cancer unit risks; (2) whether the key studies underlying the draft IRIS assessment are of requisite quality, reliability, and relevance to support the derivation of the toxicity values; (3) whether the uncertainties in EPA’s risk assessment were adequately described and if necessary, quantified.</p>
<p>24 June 2016 – Scientific Review Panel Public Meeting. Agenda item – OEHHA presents the document summarizing the derivation of the unit risk factor for Perchloroethylene. OEHHA indicates that further revisions were made based upon comments from Dr. Stanton A. Glantz, one of two lead reviewers on the Scientific Review Panel. The revisions focused on discussion and did not result in a change in the selected values.</p>	<p>2008 External panel members include Sam Kacew, University of Ottawa; Bruce Alexander, University of Minnesota School of Public Health; Margit Bleecker, Center for Occupational and Environmental Neurology, Baltimore; Linda Cowan, University of Oklahoma Health Sciences Center; Mary Davis, West Virginia University; H. Christopher Frey, North Carolina State University; Joseph Landolph, University of Southern California; M.E. Meek, University of Ottawa; David McMillan, University of Nebraska Medical Center; M. Christopher Newland, Auburn University; Julia Quint, California Department of Public Health; Gary Rosner, University of Texas; Ivan Rusyn, University of North Carolina, Chapel Hill; Rolf Schulte-Hermann, Medical University of Vienna, Austria; Irvin Schultz, Battelle Pacific Northwest Division; Robert Snyder, Rutgers; Luoping Zhang, University of</p>

	California, Berkeley; Yiliang Zhu, University of South Florida.
9 Sep 2016 – Notice of Adoption of Inhalation Unit Risk Factor for Perchloroethylene	Nov 2008, Jan 2009, April 2009 – NAS holds meetings to discuss draft report.
	Feb 2010 - NAS's National Research Council (NRC) releases Review of the Environmental Protection Agency's Draft IRIS Assessment of Tetrachloroethylene. This 100+ page document evaluated a range of topics. Key points made by the NRC were: (1) Approaches used by EPA did not adequately provide information, rationale, or clear critical analysis for including or excluding studies; (2) The study selected by EPA to evaluate neurotoxic effects was flawed and the committee disagreed with its use by EPA. More appropriate studies were identified by the committee; (3) PBPK model used to support the inhalation to oral route extrapolation was not validated against blood concentrations from oral exposures; other models are available and may be more appropriate; (4) EPA should revise its mode of action assessment for several of the cancer endpoints; (5) EPA fails to provide the full range of variation and uncertainty in relation to cancer model selection; (6) EPA should add GSH-dependent metabolism to the PBPK model. EPA reviewed and responded to all comments in the final Toxicological Review.
	Aug 2011 – EPA hosts an interagency science discussion on the review of the draft Toxicological Review and draft IRIS Summary for Tetrachloroethylene. White House offices and other federal agencies comment on draft. Comments provided by Department of Defense, Office of Management and Budget, National Toxicological Program, Agency for Toxic Substance and Disease Registry, National Institute for Occupational Safety and Health, and National Aeronautics and Space Administration.
	Oct 2011 – EPA hosts second interagency science discussion on the review of the draft Toxicological Review and draft IRIS Summary for Tetrachloroethylene. White House offices and other federal agencies comment on draft.
	Feb 2012 – EPA finalizes Toxicological Review

In contrast, OEHHA held a small number public meetings and responded to comments from a limited number of commenters. It does not appear that OEHHA conducted any meaningful external scientific peer review. As a result of this limited review, OEHHA adopted a more conservative analysis that considers both oxidative and glutathione (GSH) conjugation pathways in the metabolism of PCE. While OEHHA claims that this approach produces a more health-protective potency estimate, EPA rejected the GSH conjugation pathway during its review due to the identified variability (up to 3000-fold difference)

—CMTA-17

in the data and modeling. EPA determined that it was “not possible to disentangle the contributions of uncertainty and variability to the very large range of estimates of tetrachloroethylene GSH conjugation in humans” (p. 3-48). Instead, in developing the model for PCE, EPA included a comprehensive analysis of trichloroethene dosimetry which evaluated the urinary excretion kinetics of the two main toxic metabolites of PCE. This approach allowed EPA to account for the most harmful or biologically reactive metabolites of both the GSH and oxidative pathways while limiting the large variability observed when evaluating the GSH pathway in isolation.

CMTA-17

Department staff recently published a paper on the risk of variations in susceptibility to PCE due to genetic diversity (Spearow et al., 2017). This paper states that a more conservative evaluation of PCE that considers the GSH conjugation pathway is necessary given the unique population diversity in California. In particular, the authors claim that the Asian population lacks the pathways for metabolizing PCE and removing toxic chemical species that can lead to increased cancer risk from the body. Despite these claims, no clear evidence is provided by the authors that additional protections are needed for these populations. Instead, the authors simply imply that because of reduced GSH metabolism in individuals of Asian descent, these individuals would produce other toxic metabolites not addressed in EPA’s analysis. The authors provide no evidence in humans that additional toxic metabolites are in fact detected in this population. As described in the EPA Toxicological Assessment for Tetrachloroethylene, the most toxic chemical metabolites were evaluated and, therefore, the IRIS toxicity values are protective of all ethnicities.

CMTA-18

We question whether the Department has conducted similar analyses for other chemicals, and there is no indication that this analysis is needed for PCE. EPA’s Toxicological Review of Tetrachloroethylene was specifically developed to ensure that it is protective of all populations, including sensitive subpopulations that may be more susceptible to PCE toxicity. After an extensive review and peer review, EPA rejected the GSH pathway and determined that the current model was protective.

### Screening Numbers

The ISOR states:

OEHHA had previously developed screening levels pursuant to Health & Safety Code section 57008, but did not promulgate them, so those screening levels “have no regulatory effect and are not intended for use by regulatory agencies that have authority to require remediation of contaminated soil. The numbers are solely advisory and published as reference values” intended to be used as an aid in the estimation of cleanup costs for contaminated soil. Several of these values have not been updated to reflect current risk assessment methodology or account for revised toxicity criteria. (ISOR, page 9)

CMTA-19

The ISOR then states that the proposed regulation continues the Department’s “past practice by adopting and mandating use” of OEHHA’s screening numbers. (*Id.*) However, Section 57008 states that a screening number “is solely an advisory number, and has no regulatory effect, and is published solely as a reference value.” Under the proposed regulation, OEHHA’s screening levels will no longer be “advisory numbers” with no “regulatory effect.” The purpose of the proposed regulations is to give

OEHHA’s screening levels regulatory effect. Giving the screening levels regulatory effect does not continue the Department’s past practice—it changes the past practice.

CMTA-19  
(cont.)

Moreover, the proposed regulations appear to be in conflict with state law. As stated above, Section 57008 provides that OEHHA’s screening levels are advisory only, have no legal effect and are published solely as reference values. The proposed regulations appear to be an attempt to overturn and intent of a statute through a regulation.

CMTA-20

### Background Concentrations

Naturally occurring or anthropogenic background soil levels for many chemicals (*e.g.*, arsenic, cadmium, dioxins, PAHs, and lead) are higher than their human health risk-based screening levels under the proposed regulations. Existing practice permits risk management professionals substantial discretion to consider site-specific factors. For example, the Department’s Preliminary Endangerment Assessment Guidance Manual<sup>4</sup> states, “metals present at levels equivalent to background can be eliminated as chemicals of potential concern (COPCs) and need not be considered in the screening evaluation”. Such chemicals should be screened out on the basis of their background soil levels, consistent with current best practice, rather than according to a prescriptive standard.

CMTA-21

It does not appear that the past practice of screening out background concentrations will remain in effect. If that is the case, many urban areas in the state will exceed human health risk-based screening levels for chemicals such as lead or PAHs, even though they may be present at background levels. Strict implementation of the proposed regulations would require an increase in the amount of soil excavation and landfill disposal. This outcome would further exacerbate the problem of diminishing landfill capacity in contravention of the Legislature’s mandate in the Integrated Waste Management Act (Public Resources Code sections 40000 *et seq.*).

In 2015, the Department launched a two-year Community Protection and Hazardous Waste Reduction Initiative (CPHWRI)<sup>5</sup> to support a stated goal of 50% reduction in hazardous waste generation and disposal in California by 2025. Contaminated soils were one of four high volume hazardous waste streams specifically addressed in the CPHWRI. This project involved evaluation of alternatives to excavation and landfill disposal, including a soil washing study of heavy-metal contaminated soils, but the CPHWRI was unable to identify any cost-effective alternative technologies. The final report from this work is still pending completion and submittal to Cal-EPA and the Legislature. However, given the preliminary findings from the CPHWRI work, the Department’s proposed regulation would undermine its 50% hazardous waste reduction goal because it would tend to **increase** generation of hazardous waste from site remediation projects leading to **increased** excavation and landfill disposal.

CMTA-22

<sup>4</sup> Revised October 2015.

<sup>5</sup> <http://www.dtsc.ca.gov/HazardousWaste/CPHWRI/CPHWRI.cfm>.

## Resource Allocation and Inter-Agency Consistency

The proposed regulations lack an administrative mechanism to incorporate new or updated toxicity values as they are adopted. Rather, the ISOR indicates that updates to Appendix 1 would occur only through new rulemakings: "... periodic amendments to this regulation will be necessary to require use of a newer or updated future IRIS or OEHHA toxicity criteria." (page 14). Department staff further stated during the August 28 workshop that the agency intends to revise the regulation to incorporate new or updated values as they are adopted. USEPA<sup>6</sup>, DTSC<sup>7</sup> and the San Francisco Regional Water Quality Control Board (SFRWQCB)<sup>8</sup> tend to update their human health risk-based screening and toxicity values at least once per year. OEHHA also updates toxicity values frequently, and through multiple programs. The Department's proposed approach will require that it undertake a formal rulemaking pursuant to California Administrative Procedures Act requirements every time one of these agencies updates a toxicity value. This is a significant undertaking and an unnecessary use of staff resources.

CMTA-23

The Department's proposed regulations will also create inconsistencies with other state-wide programs. For example, the California Air Resource Board (ARB) has promulgated a consolidated table of OEHHA and ARB-approved health risk assessment values for air toxics (see: <https://www.arb.ca.gov/toxics/healthval/healthval.htm>). Some of the toxicity factors in this table are inconsistent with those listed in Appendix 1 of the proposed regulations. It therefore appears that different California programs will use different toxicity values. If the Department intends to eliminate inconsistent application of toxicity criteria between federal and state sites, it should not propose regulations that create inconsistency among toxicity values used in different state programs.

CMTA-24

## Economic Impact Analysis

The Department asserts in the ISOR that, because the proposed regulation implements existing practice, "there will be no or minimal economic impact resulting from implementation" (ISOR, page 21). Consequently, the Department did not conduct an economic impact analysis. The Department's Economic and Fiscal Impact Statement (Department of Finance Form STD 399) indicates that the proposed regulations will have no private sector cost impacts, no effect on the ability of California businesses to compete with other states and no fiscal impact on local government.

CMTA-25

Potential economic impacts should not be dismissed this way. Contrary to its sweeping conclusions, the Department's proposed regulations are likely to result in more stringent cleanup standards that will apply to California businesses but will not apply to businesses in other states. In these instances, California businesses would face more expensive cleanups placing them at a greater competitive disadvantage to businesses operating outside of California.

<sup>6</sup> USEPA Regional Screening Levels. <https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables-june-2017>

<sup>7</sup> DTSC modified-RSLs. See DTSC Health Risk Assessment Note 3. <http://www.dtsc.ca.gov/assessingrisk/humanrisk2.cfm>

<sup>8</sup> SFRWQCB Environmental Screening Levels. [http://www.waterboards.ca.gov/sanfranciscobay/water\\_issues/programs/esl.shtml](http://www.waterboards.ca.gov/sanfranciscobay/water_issues/programs/esl.shtml)

For example, the proposed rule will result in an 80 ppm lead cleanup value regardless of site-specific factors. When that cleanup value is applied to an area with urban lead background levels (commonly exceeding 200 ppm in many areas), the cost of cleanup to the state itself for orphan sites will be substantial.<sup>9</sup>

CMTA-25  
(cont.)

In addition, anchoring toxicity criteria, and potentially cleanup goals (see discussion under **Effect of the Proposed Regulations** above) to the low end of the NCP risk range ( $1 \times 10^{-6}/\text{THI} \leq 1$ ) is likely to constrain flexibility on cleanup levels and remedy selection at brownfields sites. Future land uses may not warrant such a high level of stringency and the resulting economic impacts could stall site cleanup and redevelopment, leaving these properties idle and blighted, with attendant negative impacts on local economies and government agencies. For these and other reasons, the proposed regulations are likely to qualify as a “major regulation” pursuant to Government Code section 11342 and should be subject to Department of Finance regulatory requirements for Standardized Regulatory Impact Assessments.

Accordingly, the Form STD 399 for the Economic Impact Statement of the regulation should have checked the following:

- Box A1b (Impacts small businesses), as it will impact **all** businesses, large or small, as remedial costs in California will be higher than in any other state given the same environmental setting;
- Box A1c (Impacts jobs or occupations) and A1d (Impacts California competitiveness), as it will cause California businesses to consider relocating to any one of the other 49 states that use the IRIS toxicity values in setting cleanup goals;
- Box A1e (Imposes reporting requirements) as it will require doubly “screening” with OEHHA toxicity values and 1E-06 risk levels regardless of the reasonable utility of duplicating such effort, as many federal Superfund sites already screen with USEPA regional screening levels;
- Box A1f (Imposes prescriptive instead of performance), as it removes advances in science from the regulatory screening and cleanup goal equations by demanding fixed (and soon to be outdated) OEHHA toxicity values to the rejection of all other future and/or better science; and,
- Should **not** have written in that “None of the above” will be impacted because “Promulgates existing practice in use since at least 1994.” As explained above, these OEHHA toxicity values were not an ARAR, and “existing practice” does not meet with immediate public acceptance.

CMTA-25  
(cont.)

It is critical to recognize the significant monetary burden attached to overly aggressive remediation policies. Setting lower clean up levels in California, without a scientific reason to do so, will result in higher operation costs. The Department checked “No” to “Will the regulation affect the ability of

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<sup>9</sup> See for example: “Spatial analysis of bioavailable soil lead concentrations in Los Angeles, California” *Environmental Research, Volume 110, Issue 4, May 2010, Pages 309-317*, Jun Wu, Rufus Edwards, Xueqin (Elaine) He, Zhen Liu, Michael Kleinman. This paper indicates that total and bioavailable Pb concentrations near freeways and major arterials were significantly higher than those collected elsewhere.

California businesses to compete with other states by making it more costly to produce goods or services here.”

Further, item B(5) Estimated Costs “Are there comparable Federal regulations?” was left blank on the Form STD 399, which does not acknowledge Superfund and its accompanying Federal guidance. Lastly, the STD 399 question “Explain the need for State regulation given the existence or absence of Federal regulations” was also not answered. The public should be fully informed that the Federal government addresses this and, at a minimum, the difference between the Federal and State regulations should be entered on page 2 of the STD 399.

CMTA-26

### **Retroactivity**

While the ISOR asserts that the proposed regulations would not be applied retroactively, Department staff acknowledged during the August 28 workshop that they could lead to reopening remedial action decisions and requiring additional cleanup at existing sites as non-discretionary Table 1 toxicity criteria are substituted for previously designated criteria. This potential exists at all sites subject to five year reviews under the NCP. Department staff also suggested that the agency could reopen a site in response to an inquiry or petition from any interested party. It is reasonable to expect that the proposed regulations will lead to new inquiries and petitions, especially at high profile site cleanups. Thus, contrary to the Department’s assertions in the ISOR, these outcomes would constitute retroactive application of the proposed regulations, made mandatory by the prescriptive nature of the proposed toxicity criteria selection hierarchy.

CMTA-27

Retroactive application of the proposed regulations would result in imposition of new cleanup costs at existing sites. These costs should be included in a meaningful evaluation of the potential economic impacts of the proposed regulations.

### **CEQA Compliance - Exemption**

The proposed regulations are not exempt from CEQA and the Department is required to prepare an EIR to evaluate the serious environmental impacts on, for example, landfill capacity and the marketability of contaminated and formerly contaminated properties. The Department’s Notice of Proposed Action claims that the proposed regulation is exempt from CEQA review under the “common sense exemption,” California Code of Regulations, Title 14, section 15061(b)(3). The common-sense exemption applies only “where it can be seen *with certainty* that there is *no possibility* that the activity ... may have a significant effect on the environment.” 14 Cal. Code. Regs. § 15061(b)(3) (emphasis added). If legitimate, reasonable questions can be raised about whether the project might have a significant impact, the common-sense exemption does not apply. *California Farm Bureau Federation v. California Wildlife Conservation Bd.* (2006) 143 Cal.App.4<sup>th</sup> 173.

CMTA-28

The Department’s proposed regulation is likely to have numerous and significant environmental impacts and, consequently, the Department’s action is not exempt from CEQA. As discussed above, the proposed regulation does not constitute a mere codification of existing practice and will result in increased volumes of solid and hazardous waste being sent to California landfills for disposal, placing

additional pressure on already overtaxed landfill capacity. Further, the proposed regulation's effect on the cost of restoring brownfield sites could further stymie the State's redevelopment efforts, resulting in more blighted and underutilized properties. The Department has also failed to consider the potential budgetary and staffing impacts on its own site cleanup programs from new or expanded orphan sites that would likely result from anchoring risk assessment inputs at the low end of the NCP risk range. For these reasons, the Department's proposed regulations are not entitled to the common-sense exemption and the Department should engage in full CEQA review to reach an informed decision that considers and balances all of the regulation's potential direct and indirect impacts. 14 Cal. Code Regs. § 15064(d).

CMTA-28  
(cont)

### **CEQA Compliance – Alternatives Assessment**

The public notice and the ISOR indicate that the Department evaluated 3 potential alternatives for the proposed regulations:

1. The initial informal proposed regulations, released in November, 2016, which specified use of the "most protective" toxicity criteria;
2. A second alternative in response to public comments on the informal proposal, which included a variance provision to allow immediate use of updated toxicity criteria; and,
3. The alternative upon which the proposed regulations are based, which includes the most prescriptive toxicity criteria selection hierarchy among the three alternatives.

Apparently, the Department rejected Alternative 2 without any public review or comment. To our knowledge there has never been a clear articulation of Alternative 2. The public notice describes the Department's evaluation of alternatives as follows:

CMTA-29

"From the input received in the workshop and comments, the Department developed Alternative 2. It "ranked" the primary toxicity criteria sources; included an exclusion for certain metallic elements and a variance procedure; and clarified the application of the 1x10<sup>-6</sup> cancer risk level and a HI of 1 for non-cancer risk contaminant screening levels and remediation goals. Upon further internal deliberation and consultation with other state and federal agencies, the Department determined some of the changes incorporated into Alternative 2 were impracticable or did not adequately factor in California's unique demographic in selecting appropriate criteria, and significantly changed current and historical practice for selecting toxicity criteria. Accordingly, the current proposed regulation (Alternative 3) is consistent with current and past practice, applies the best scientific practice, and factors in California's unique demographic in selecting toxicity criteria. In contrast to Alternative 1, it also does not include specific language regarding application of the 1x10<sup>-6</sup> cancer risk level and HI of 1 for non-cancer risk to set remediation goals, but instead refers to the National Contingency Plan for that process."

A full CEQA EIR process would be well suited for disclosing the full details of all 3 alternatives and other potential alternatives that should be considered, including a “no action” alternative.

It appears that a full EIR process is essential in this case because the proposed regulations would impact risk assessments used to establish action levels, points of departure, screening levels, and remediation goals. It also appears that the outcome at any site subject to the proposed regulations would be more restrictive than for a comparable site subject to the NCP but located outside of California. By virtue of driving lower cleanup levels, the proposed regulation would lead to more extensive remediation, including increased soil and groundwater extraction, increased media treatment and increased offsite disposal with attendant environmental impacts including increased energy consumption, greenhouse gases, criteria pollutants and toxic air contaminants from heavy duty equipment, increased storm water runoff and impacts on landfill capacity. These and other potential impacts may trigger site-specific CEQA reviews, but that fact does not relieve the Department of its obligation to consider the potential statewide impacts of the proposed regulations.

CMTA-29  
(cont.)

As stated above, the fact that these regulations would likely lead to an increase in land disposal of remediation wastes is by itself sufficient reason to conduct a full CEQA EIR. Contaminated soil is already the largest single category of hazardous waste disposal to land in California. Certainly, lower soil cleanup levels would lead to a significant increase in land disposal in the absence of cost-effective alternatives. To the extent that any cost-effective alternatives may exist, they should be thoroughly evaluated. In addition, the Department should be keenly aware of growing resistance to the perception of shifting environmental burdens from one community to another through excavation, transportation and re-disposal of contaminated soils. These issues and potential environmental impacts cannot be fully evaluated except through an EIR.

If adopted, this proposal will require vast amounts of contaminated soil to be treated as hazardous waste in California. However, the same soil may not be hazardous when it is transported across borders with adjoining states. The rule subjects Californians to unnecessary costs, including excavation, transport, and disposal, but the final disposition may result in disposal pursuant to less demanding regulatory standards in adjoining states.

CMTA-30

An EIR is also necessary to evaluate the impact of the proposed regulations on property locations throughout California that have been impacted by past human activities. Before adopting the proposed regulations, the Department should prepare complete economic and environmental impact assessments of applying more restrictive remediation levels statewide, including in residential neighborhoods where home owners’ principal assets may be the equity in their homes that could be devalued as a result of an expanded remedial action project. The proposal put forth by the Department has not included any discussion of artificially depressed property values, including residential properties owned by unsuspecting homeowners. Adoption of this regulation does not consider areas where legacy and ambient background levels exceed the cleanup value.

**From:** Lenny Siegel  
**To:** [toxcriteria@dtsc.ca.gov](mailto:toxcriteria@dtsc.ca.gov)  
**Cc:** [Depies, Kevin@DTSC](mailto:Depies, Kevin@DTSC)  
**Subject:** Comment on Toxicity Criteria Rule  
**Date:** Wednesday, September 20, 2017 7:33:17 AM  
**Attachments:** [Toxicity Criteria communities letter.pdf](#)

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Please see the attached comment letter signed by community representatives from throughout California.

In addition to the comments in the letter, I urge you to add a “purpose” section. It would improve public understanding of the rule. ] CPEO-01

Lenny Siegel

--

Lenny Siegel  
Executive Director  
Center for Public Environmental Oversight  
a project of the Pacific Studies Center  
P.O. Box 998, Mountain View, CA 94042  
Voice/Fax: 650/961-8918  
<[lsiegel@cpeo.org](mailto:lsiegel@cpeo.org)>  
<http://www.cpeo.org>

On behalf of the communities in which we live and work, we the undersigned are writing to support the proposed regulation, Toxicity Criteria for Human Health Risk Assessments Screening Levels and Remediation Goals Rule (Department Reference Number: R-2016-08; Office of Administrative Law Notice File Number: Z-2017-0725-08). This regulation will formalize and thus make more enforceable the long-standing practice of utilizing California's own toxicity criteria where federal criteria are less stringent. California regulations take into account potential health risks to the public due to toxic exposures at levels known to put people's health at risk, especially pregnant women and fetuses. This practice is essential to protecting Californians against toxic exposures and for providing a baseline of consistency at cleanup sites throughout the state.

CPEO-02

Despite the efforts of many competent, well-meaning people, we believe the federal system for setting toxicity criteria is biased in favor of heavily resourced institutions representing entities that produce, use, and market hazardous substances. We recall the case of perchlorate, where polluters simply funded another study to debunk a study they earlier supported because they were dissatisfied with the result. This delayed and weakened federal exposure limits. It also is an example of how organizations may buy study conclusions. We also note the observation of the National Research Council committee that reviewed U.S. EPA's Integrated Risk Information System.

"Most public comments on draft IRIS assessments have come from industry or parties representing the interests of entities that produce, use, and release possibly toxic substances. Indeed, almost all the public input - written and oral - received by the present committee has come from trade organizations. Furthermore, from January 2011 to October 2013, over 100 distinct substantive comments were submitted to the IRIS program. Representatives of entities that produce, use, or release the studied substances submitted over 80 comments. In that period, only a few comments were submitted by public-interest organizations concerned with the environment. Comments submitted by concerned citizens or entities apparently representing them contained little or no specific scientific information that might influence the IRIS program's findings."

CPEO-03

The system is biased in favor of polluters, so to counteract that bias we support California's efforts to ensure that reasonable, protective standards apply to all hazardous waste and toxic substance cleanups within the state.

Caroline Cox, Center for Environmental Health, Oakland  
Joan Davidson, Sierra Club Open Space Task Force, Palos Verdes  
Rick Herbert, Berkeley  
Marylia Kelley, Tri-Valley CAREs, Livermore  
Bob Moss, Barron Park Association Foundation, Palo Alto  
Penny Newman, Center For Community Action & Environmental Justice  
Lenny Siegel, Center for Public Environmental Oversight, Mountain View  
Peter Strauss, Peter M. Strauss & Associates, San Francisco  
Eric Sunada, San Gabriel Valley Oversight Group, Alhambra  
Andria Ventura, Clean Water Action



September 20, 2017

To: Kevin Depies, Project Manager  
Department of Toxic Substances Control

Subject: Comments on draft rule, Toxicity Criteria for Human Health Risk Assessments, Screening Levels and Remediation Goals.

**Staff**

**Cynthia Babich**  
*Director*

**Board of Directors**  
**Florence Gharibian**  
*Board Chair*

**Cynthia Medina**  
*Assistant to the  
Director/Resident*

**Lydia Valdez**  
*Homeowner/Resident*

**Brenda Bibee**  
*Volunteer Coordinator*

**Mallory Graves**  
*Board Member*

**Lizabeth Blanco**  
*Homeowner/Resident*

**Emeritus Board**

**Barbara Stockwell**  
*Homeowner*

**In Memoriam**  
**Nick Blanco**  
*Homeowner/Resident*

Thank you for providing an opportunity to comment on the Department of Toxic Substances Control's (DTSC) proposed Rule; Toxicity Criteria for Human Health Risk Assessments, Screening Levels and Remediation Goals. The rule will enhance the clarity, predictability and enforceability of the process of conducting Human Health Risk Assessments and will also aid in achieving consistency and predictability in establishing site remediation goals. The Del Amo Action Committee (DAAC), a non-profit group representing the communities affected by the Del Amo/Montrose Superfund sites, supports the application of the Rule in determining ARAR's for hazardous substance releases at properties that are under federal oversight. The rule will be applicable to many sites including the Montrose/Del Amo Superfund sites and associated contamination on several properties near or adjacent to our community. We need DTSC's support in remediating this contamination.

DAAC-01

The Rule excludes Total Petroleum Hydrocarbons and TPH PPRTV's. Total Petroleum Hydrocarbons are defined in the draft Rule as a large family of several hundred compounds derived from crude oil. Community members often find the routine use of complicated abbreviations confusing. The first challenge in preparing this correspondence was to find a definition for PPRTVs (Provisional peer-reviewed toxicity values for complex mixtures of aliphatic and aromatic hydrocarbons). In excluding both TPH and TPH PPRTVs the Rule excludes many of the toxic chemicals found throughout California and specifically in the Los Angeles area where petroleum refineries and associated businesses are potentially responsible for soil and groundwater contamination. Please provide an explanation for why these chemicals are excluded from the rule.

DAAC-02

Contaminated properties are often contaminated by a mixture of chemicals, possibly from several industrial processes. The understanding of the impact on health from several co-mingled toxic chemicals on a contaminated property is limited. A report addressing this was published by the National Resources Defense Council and the Science and Environmental Health Network in February 2012. The report is entitled Strengthening Toxic Risk Assessments to Protect Human Health. The Report's authors are; Sarah Janssen, M.D. P. HD M.P.H., Jennifer Sass, P.H.D, Ted Schettler, M.D.,M.P.H. Gina Solomon, M.D. M.P.H.

DAAC-03

The Report includes this opening statement: Without additional modifications, risk assessment might become irrelevant in many decision contexts.

It includes four recommendations:

1. Identify and incorporate variability in human exposure and vulnerability into health assessments, so that all people are better protected.
2. When Information is missing or unreliable, use science based default assumptions that protect public health rather than waiting for more data. Speed up the chemical assessment and decision making process.
3. In assessing the risk of chemicals, incorporate information about the potential impacts of exposure to multiple chemicals. Consider other factors, such as exposure to biological and radiological agents and social conditions.
4. Because the population is exposed to multiple chemicals and there is a wide range of susceptibility to chemical exposures, it cannot be presumed that any – even low- exposures are risk-free. It should be assumed that low levels of exposures are associated with some level of risk, unless there are sufficient data to contradict this assumption.

DAAC-03  
(cont.)

All of the recommendations are directly relevant to the co-mingled contamination from multiple dangerous chemicals present in the soil, soil vapor and groundwater at and surrounding the Del Amo/Montrose Superfund sites. “Some level of risk” is an operable phrase in this environment.

Adequate site characterization is also critical in site mitigation. Our experience in evaluating the proposed mitigation plan for the Ecology Control Industries property in the Harbor Gateway convinced us that more work is needed to ensure that site characterization is conducted using guidelines that are clear and consistent. Standard templates must always consider the need for site characterization from multiple chemicals with differing detection and monitoring methods. Responsible parties may be reluctant to do adequate site characterization due to the costs associated with this work; which is why clarity about the application of this Rule in determining ARAR’s for hazardous substance releases at properties that are under federal oversight is critical.

DAAC-04

DAAC-05

Thank you for providing the opportunity to comment on this important Rule. We appreciate your consideration of our comments

Cynthia Babich  
Director, Del Amo Action Committee

Florence Gharibian  
Chairperson, Board of Directors Del Am Action Committee  
([Florencegharibian@yahoo.com](mailto:Florencegharibian@yahoo.com))



DEPARTMENT OF THE NAVY  
COMMANDER NAVY REGION SOUTHWEST  
937 N. HARBOR DR.  
SAN DIEGO, CA 92132-0068

IN REPLY REFER TO:

5090  
Ser N40 / 893  
September 19, 2017

Mr. Kevin Depies  
Department of Toxic Substances Control  
8800 Cal Center Drive  
Sacramento, California 95826

Dear Mr. Depies:

SUBJECT: COMMENTS ON CALIFORNIA'S PROPOSED RULE ON TOXICITY CRITERIA

The United States Department of Defense (DoD) provides these comments in response to the Department of Toxic Substance Control (DTSC) request for public comment of Human Health Risk-based Screening Levels, Action Levels, and Remediation Goals by September 20, 2017. These DoD comments should be read in conjunction with the comments provided on January 19, 2017 (enclosure (1)).

Enclosure 2 of this letter contains DoD's comments on the proposed regulation and emphasize DoD's significant concerns that the proposed regulation arbitrarily ignores the best science available on toxicological data, is contrary to long-established federal and state guidance, and contains implementation issues that will likely prolong cleanup and will not actually contribute to the actual protection of human health.

DoD recommends using toxicity criteria that are the most scientifically valid for the exposure scenario and route being examined; rather than locking in Office of Environmental Health Hazard Assessment's Appendix I unit risk factors in all cases where they exist, even if more current United States Environmental Protection Agency's Integrated Risk Information System risk factors are available. We believe that DTSC should focus on using the most up-to-date, peer reviewed, science when developing human health risk-based action level and remediation goals.

The DoD is committed to achieving site cleanup that is protective and in full compliance with federal and state regulations and using the most valid science available. On behalf of the military services in California, please consider this input to achieve the most efficient use of resources to remediate contaminated sites.

If you have any questions or concerns regarding these comments, my points of contact in this matter are Mr. Michael Huber who can be reached at COMM: (619) 532-2303 and Mr. David Bell who can be reached at COMM: (707) 424-8279.

Sincerely,

C. L. STATHOS  
Deputy Regional Environmental Coordinator  
By direction  
of the Commander

- Enclosures: 1. COMNAVREG SW Itr 5090 Ser N40 056 of January 19, 2017  
2. DOD Comments on DTSC's Toxicity Criteria for Human Health Risk-Based Screening Levels, Action Levels and Remediation Goals



**DEPARTMENT OF THE NAVY**  
COMMANDER NAVY REGION SOUTHWEST  
937 N. HARBOR DR.  
SAN DIEGO, CA 92132-0058

IN REPLY REFER TO:

5090  
Ser N40/056  
January 19, 2017

Mr. Kevin Depies  
Department of Toxic Substances Control  
8800 Cal Center Drive  
Sacramento, California 95826

Dear Mr. Depies:

**SUBJECT: TOXICITY CRITERIA FOR HUMAN HEALTH RISK-BASED SCREENING LEVELS, ACTION LEVELS, AND REMEDIATION GOALS**

The United States Department of Defense (DOD) provides these preliminary comments in conjunction with the comments invited by the Department of Toxic Substance Control (DTSC) at the Public Workshop held on December 12, 2016 on the proposed regulations specifying the toxicity criteria for human health risk-based screening levels, action levels and remediation goals.

The DOD provides these preliminary comments with the understanding that DTSC has not formally initiated a rule-making process. While these comments may be considered by DTSC to revise the proposed regulation, we recognize DTSC will not be providing a response to these comments. Therefore, the DOD would expect to have an opportunity to comment on a future formal regulatory rule-making and receive a subsequent response to those comments.

The DOD comments on the proposed regulation are:

The proposal focuses on using the “most protective of the following three toxicity criteria”. However there is no definition of “most protective”. Some could interpret this to be the “lowest” level, while that may not in fact be the case. DOD proposes adding a definition of “most protective”, which focuses on using toxicity criteria that are the most scientifically valid for the exposure scenario and route being examined. The DOD recommends the DTSC focus on using the most up-to-date peer reviewed science when developing human health risk-based action level and remediation goals

DOD-01

DOD-02

The terms “screening levels, action levels and remediation goals” used in the proposal are not defined in the regulations. These three terms should be defined so that responsible parties can more fully understand their application to the site remediation process.

DOD-03

The proposed regulation is contrary to established Environmental Protection Agency Office of Solid Waste and Emergency Response (OSWER) guidance regarding the preferred toxicity value to be used in risk assessment and management. Several OSWER directives document significant work to provide a consistent and scientifically sound approach regarding the use of toxicity values. This cumulative guidance ensures the use of the most credible, recent toxicity assessments that are protective of human health.

DOD-04

5090  
Ser N40/056  
January 19, 2017

The proposed DTSC regulation could force the use of outdated toxicity criteria, potentially causing cleanup sites to be unnecessarily expanded into areas not meeting OSWER criteria. The proposed DTSC regulation could even result in the use of toxicity criteria that has not been peer-reviewed, and thus not as scientifically valid.

DOD-05

If the proposed rule is implemented, it is unclear how peer-reviewed scientific studies would be entered into the state's chemical database, how dated information could be removed, or how to proceed in the event a chemical is not listed in any of the three sources listed.

DOD-06

The DOD is committed to achieving site cleanup that is protective and in full compliance with federal and state regulations and using the most valid science available. On behalf of the military services in California, please consider this input to effectuate the most efficient use of resources to remediate contaminated sites.

If you have any questions or concerns regarding these comments, my points of contact in this matter are Mr. Michael Huber who can be reached at COMM: (619) 532-2303 and Mr. David Bell who can be reached at COMM: (707) 424-8279.

Sincerely,



C. L. STATHOS  
Deputy Regional Environmental Coordinator  
By direction  
of the Commander

## DOD Comments on DTSCs Proposed Rule on Toxicity Criteria for Human Health Risk-Based Screening Levels, Action Levels and Remediation Goals

### 1. Arbitrarily Sets Toxicity Criteria Values & Ignores More Recent “Best Science” Data

**Comment** - The proposed rule arbitrarily elevates California Office of Environmental Health Hazard Assessment (OEHHA) toxicity criteria values above more recent and nationally established “best science” toxicity data.

DOD-07

**Discussion** - This proposed rule arbitrarily ignores more recent and nationally established “best science” data, and does not include a mechanism to update the toxicity values. The proposed regulation is contrary to established EPA Office of Solid Waste and Emergency Response (OSWER) guidance regarding the toxicity value used in health risk assessment and management. Several OSWER directives document the well-founded and long-standing approach to use the best available science as the basis for selecting toxicity criteria. This cumulative guidance ensures the use of the most credible, relevant, and recent toxicity criteria in order to protect human health. The USEPA OSWER Directive 9285.7-53 “Human Health Toxicity Values in Superfund Risk Assessments, 2003”, documents the current accepted methodology regarding use of toxicity criteria. This methodology conceived by the USEPA and supported by the Environmental Council of States (ECOS), bases selection of toxicity criteria on the best science. The proposed regulation as written eliminates the intent of, and flexibility of OSWER Directive 9285.7-53 to ensure the use of more recent, credible and relevant data to establish a toxicity value/criteria. The proposed regulation may in fact force the use of outdated toxicity criteria, for certain Contaminants of Potential Concern (COPC), potentially causing cleanup action at areas not meeting OSWER criteria. As written, the toxicity criteria in the Appendix to the regulation are static, and not flexible, and could result in the use of criteria that is not based on best science, and thus conflicts with EPA guidance.

DOD-7.1

California is a member of the ECOS, which is the national non-profit, non-partisan association of state and territorial environmental agency leaders. In the issue paper by the ECOS-DoD Sustainability Work Group - *Identification and Selection of Toxicity Value/Criteria for CERCLA and Hazardous Waste Site Risk Assessments in the Absence of IRIS Values* (2007), the ECOS stated that “The Work Group supports as an overriding principle, that the States, EPA, DoD, and other risk assessors should not be seeking to identify higher or lower toxicity values. Rather, the effort should continue to be to identify the best, or most scientifically defensible, toxicity value.” The proposed regulation disregards this nationally developed and accepted practice of best science.

DOD-7.2

The proposed regulation sets an inappropriate precedent regarding independent science. In the past decade, the USEPA has placed continued emphasis on scientific integrity. The EPA’s policy that favors ‘best science’ promotes the continued evaluation of toxicity criteria to ensure the most scientifically defensible result. DTSC’s proposed regulation creates a disincentive for toxicologists to re-evaluate existing toxicity criteria if a new evaluation might result in a less stringent value. In addition, when developing new toxicity criteria or revising old criteria, there might be an inclination to choose a less appropriate study that would then require an additional

DOD-7.3

safety factor in the calculation in order to produce a more stringent, but less scientific, result. Hence, the regulation could promote the development of less-scientifically based values. In fact, the latest and best science may be intentionally ignored. The result thus creates professional conflicts for those researching toxicity in California that might feel pressured to override the best science.

DOD-7.3  
(cont.)

An example of the manifestation to use most stringent rather than best science-based toxicity criteria is evident by noting that trichloroethylene (TCE) is not included in the Appendix I to the regulation and thus the OEHHA toxicity criteria would not be considered and selected in the first tier hierarchy of the proposed regulation. Although OEHHA produced toxicity criteria for TCE (i.e., IUR and SFo), DTSC may have opted not to include it in Appendix I because the IRIS values for TCE are “more stringent.” This appears to support a false premise that the science of toxicity characterization only goes “one way” and toxicity criteria can only ever become “more stringent.” Science indicating a better understanding of toxicity, to include a chemical being less toxic than previously thought, does not appear allowed under the proposed rule.

DOD 7.4

## 2. Conflicts with the California Health and Safety Code (CHSC)

**Comment** - The proposed regulation is in conflict with CHSC Section 25356.1.5, subdivision (c), which specifies that human health risk assessments “include the most current sound scientific methods, knowledge, and practices of public health and environmental professionals.”

DOD-08

**Discussion** - The proposed hierarchy for selecting toxicity criteria, presented in section 69021, does not allow for “best available science” to be considered until the third hierarchy tier is reached. This rigidity would result in the use of toxicity criteria even if more current and scientifically based studies were available and is not in compliance with the CHSC. In addition, if at some point in the future, the EPA or other states develop more credible or relevant toxicity criteria, a remedial action would then not be based on the most current sound scientific knowledge. Decision documents and remedial action would be at risk of delay for up to a year to wait for revision to the Appendix and regulation to include the most current sound scientific knowledge.

DOD-09

Inclusion of numerical cancer potency values, and non-cancer health hazard values as an Appendix to the proposed regulation submitted for rule making, and the supporting documents for the analytes in the Appendix infer that the toxicological studies are put forth by DTSC for review and comment. The time and effort to review the scientific basis for the 67 analytes in the regulation appendix is not reasonable in the 45 day comment period.

DOD-10

## 3. Unclear intent and legal effect on the CERCLA and NCP process.

**Comment** - Section 69022(c) states that “All human health risk-based remediation goals for response actions conducted under Health and Safety Code Division 20, Chapter 6.8 shall comply with Health and Safety Code section 25356.1.5(a)(1).” This referenced section in turn requires that “Any response actions taken or approved pursuant to this Chapter shall be based upon, and no less stringent than, all of the following:” Listed thereafter are specified provisions of the NCP. It is unclear what specific provisions in the NCP relevant to the establishment of

DOD-11

remediation goals are being referred to and/or incorporated. In addition, 69020(c)(5) allows for site-specific remediation goals and 69020(b) states "This Chapter clarifies, without changing, the Department's existing practices for human health risk assessment, and for deriving both human health risk-based screening levels and human health risk-based remediation goals." It is unclear what the legal effect of the proposed regulation will have on the CERCLA and NCP process.

DOD-11

DOD-12 — **Discussion** - The regulation as written will cause debate and consume staff time. It conflicts with the application of the nine NCP feasibility study evaluation criteria in several ways. Inclusion of specific toxicity criteria in a regulation seems to blur the lines between the two threshold NCP criteria, which are (1) overall protection of human health and the environment, and (2) compliance (or waiver) with ARARs. If ARARs are not available or are determined to not be protective, risk-based goals that provide protection of human health and the environment can be developed. It appears, however, that DTSC is attempting to insert its proposed regulation into both the CERCLA risk assessment and ARAR process. This does not appear to be consistent with the NCP, and it is even unclear if the DTSC regulation, if finalized, would qualify as an ARAR.

DOD-11  
(cont.)

#### 4. Unclear Implementation of Toxicity Criteria

**Comment** - The regulation as written is unclear regarding the use of toxicity criteria identified in the regulation for developing human health risk-based remediation goals, how future studies would be incorporated, how dated information could be removed, or how to proceed in the event a chemical is not listed in any of the three sources listed. Section 69020(b) states that "This Chapter adopts toxicity criteria for all 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 this Chapter." The same section goes on to state that "This Chapter does not replace applicable Maximum Contaminant Levels (MCLs) established under Health and Safety Code section 116365 or Title 42 United States Code section 300g as remediation goals.", and leaves silent the relationship between the requirements of this regulation and other federal or State requirements.

DOD-13  
and 14

DOD-15

DOD-14 — **Discussion** - The proposed regulation lacks clarity as to how new peer-reviewed scientific studies would be entered into the selection hierarchy, how dated information could be removed, or how to proceed in the event a chemical is not listed in any of the three sources listed. There are COPCs/analytes in Appendix I of the regulation that are already out dated, have recently been updated, and/or have upcoming EPA review, such as lead, polycyclic aromatic hydrocarbons (PAHs) and chromium. Also related, section 69020.(c)(3) states that the IRIS values to be used are from those issued September 30, 2017 which if promulgated, would codify that only the 2017 IRIS values are to be used.

DOD-13

DOD-13  
(cont.)

#### 5. No Defined Peer Review Process

**Comment** – There is no definition or process outlined for peer-review for future "OEHHA's peer reviewed" toxicity values when new values are required.

DOD-16

**Discussion** - It is critical that the rule include language that requires all values to be have undergone a scientific peer review process that is open and transparent. It is DoD policy to select toxicity criteria following a tiered approach in which only values that have undergone scientific peer review can be considered, per DoD Instruction 4715.18.

DOD-16  
(cont.)

While within the EPA's current IRIS process, there is ample opportunity for selection of a peer review committee and development of charge questions, the proposed rule lack adequate details on a peer-review process for future values.

## 6. Unclear Update Process

**Comment** - The process for adopting and implementing changes to the state's approved list of toxicity values should be clarified.

DOD-17

**Discussion** - The whole purpose of the rules seems to be to codify a list of existing (and sometimes dated) toxicity values without outlining a process for revision or update when new science is available. The only means outlined to update an existing value appears to be approval from the DTSC, per 69021(c), but even this is unclear as subpart c is aimed at "Toxicity Criteria from another source."

## 7. These Regulations are Unnecessary

**Comment** - The proposed regulation is unnecessary as the OSWER Directives allow for and directs the use of best available science, and thus the use of toxicity values protective of human health.

DOD-18

**Discussion** – The USEPA OSWER Directive 9285.7-53, quoting OSWER Directive 9285.7-16, "...IRIS is not the only source of toxicology information, and in some cases more recent, credible and relevant data may come to the Agency's attention. In particular, outside parties may bring an Agency, toxicological information other than that in IRIS. Such information should be considered along with the data in IRIS in selecting toxicological values; ultimately, the Agency should evaluate risk based upon its best scientific judgement and consider all credible and relevant information available to it." A recent example is Dana Stalcup's memo "Considering a Non-cancer Oral Reference Dose for Uranium for Superfund Human Health Risk Assessments" of December 21, 2016 that recommends use of ATSDR's chronic MRL for the chemical effects of uranium rather than the IRIS value. Thus, when appropriate, current OSWER guidance does prescribe the use of an OSWER Tier 3 value rather than a Tier 2 or Tier 1/IRIS value. Thus knowing current regulatory guidance and direction exists to prescribe the use of best science, the regulation purports to implement an unjustifiable and unnecessary "most stringent" methodology.

In addition, there is a lack of studies and a scientific basis to justify the proposed specific criteria and protection of the California population, as detailed in the ISOR. Also, federal guidance and CERCLA already require accounting for and addressing potential exposed populations when evaluating risk to human health.

DOD-19

**From:** [Hellmann-Blumberg, Uta@DTSC](mailto:Hellmann-Blumberg_Uta@DTSC)  
**To:** [toxcrateriarule](mailto:toxcrateriarule)  
**Cc:** [Gettmann, Kimberly@DTSC](mailto:Gettmann_Kimberly@DTSC); [Depies, Kevin@DTSC](mailto:Depies_Kevin@DTSC)  
**Subject:** Comments on the Proposed Regulation for Toxicity Criteria for Human Health Risk Assessment  
**Date:** Wednesday, September 20, 2017 5:09:14 PM

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To whom it may concern:

I have two specific suggestions regarding language in the Initial Statement of Reasons (ISOR):

Section 69020, subdivision (e) – page 13. Proposed replacement language (in place of the ATSDR definition):

“TPH is a term used in environmental investigations for a parameter that provides a rough measure of the contaminant concentration in environmental media (soil, groundwater, surface water, air) that results from the release of petroleum hydrocarbon mixtures, which consist of hundreds or thousands of related organic compounds. Use of TPH in cleanup and for risk-based decision making requires an acceptable combination of analysis method(s), definition of fractions and toxicity criteria for hydrocarbon fractions.”

Section 69021, subdivision (c) – page 15, second paragraph on TPH that singles out the PPRTVs to be specifically excluded.

Problem statement: The specific problem here is the language in the second line: “*excludes the TPH Mixture PPRTVs from the list of **available** criteria*” [emphasis added] which indicates that selecting a PPRTV non-cancer toxicity factor for one or more TPH fractions would not be an option even in a situation where it would be appropriate (e.g., where regulators and responsible parties agreed on the hydrocarbon fraction-based approach and analytical methods). The remainder of the paragraph is not very clear but alludes to the problem that TPH toxicity criteria cannot be evaluated by themselves without considering the proposed analytical method/s. The focus on the TPH PPRTVs also leaves other questions regarding c-level criteria in general unanswered, for example on selection and use of criteria from other states.

Proposed replacement language: “Subdivision c) provides criteria for identifying additional sources of toxicity criteria that may be acceptable when a) or b) level criteria are not available. It does not provide a comprehensive list of acceptable sources and it does not establish a hierarchy for sources within this section. Also, consistent with the Department’s long-standing current practice and since neither OEHHA nor IRIS have developed toxicity criteria for evaluating petroleum hydrocarbon mixtures, the Department will determine whether proposed toxicity criteria for TPH fractions are consistent with Health and Safety Code section 25356.1.5 subdivision (c). Provided the selected toxicity criteria are also compatible with analysis methods and fraction designations, they may be used as approved by the Supervising Toxicologist of the Human and Ecological Risk Office or her or his designee.”

HB-01

HB-02

HB-02  
(cont.)

Additional Comment: Neither the existing nor the proposed language can adequately explain the rationale underlying the statement "*excluding the TPH PPRTVs*" that is in parentheses in the "Proposed Regulation Text" (Section 69021 Applicable Toxicity Criteria, page 3 of 4, item c on line 8). It is clear that TPH toxicity criteria are a special case due to the complex nature of the mixtures evaluated based on TPH. If there is a truly compelling rationale for "*(excluding TPH PPRTVs)*" it needs to be spelled out more clearly in the ISOR; otherwise the statement should be removed from section (c) of the regulation. An alternative to discussing TPH might be to state that the proposed regulation does not apply to complex mixtures and define "complex mixtures" as mixtures containing more than 100 individual chemicals regardless of whether there is a perceived conflict or not.

HB-03

Thank you for your work on this rule making effort.

Sincerely,

Uta Hellmann-Blumberg, PhD  
Staff Toxicologist  
Department of Toxic Substances Control  
Human and Ecological Risk Office  
8800 Cal Center Drive  
Sacramento, CA 95826  
[Uta.Hellmann-Blumberg@dtsc.ca.gov](mailto:Uta.Hellmann-Blumberg@dtsc.ca.gov)  
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September 20, 2017

Mr. Kevin Depies  
Department of Toxic Substances Control  
8800 Cal Center Drive  
Sacramento, CA 95826  
E-mail: Kevin.Depies@dtsc.ca.gov

**Subject: Comments on Proposed Regulations Specifying the Toxicity Criteria for Human Health Risk Assessments and Health-Based Decision-Making**

Dear Mr. Depies:

Integral Consulting Inc. (Integral) appreciates the opportunity to provide comments to the California Department of Toxic Substances Control (DTSC) pursuant to the recent request for public input on the draft final proposed *Rulemaking Draft Regulation Establishing Toxicity Criteria for Risk Assessments, Screening Levels and Remediation Goals*. The draft final proposed rulemaking (the proposed rule) includes changes to California Code of Regulations, Title 22, Division 4.5, Environmental Health Standards for the Management of Hazardous Waste, Chapter 51.3, Article 1, Sections 69000.1–69000.3. The proposed rule specifies required toxicity criteria when establishing human health risk-based screening levels, action levels, and remediation goals. However, the proposed rule, as currently written, is not clear or explicit enough regarding 1) the process of selecting toxicity criteria, 2) the applicability of the rule to sites with existing decision documents, 3) the applicability of the rule to sites that are under the lead of agencies other than DTSC, 4) the process for updating specified toxicity criteria, and 5) the applicability of the rule to non-chronic exposures.

Feeds  
INTG-01,  
-02, -03,  
-04

This letter provides specific comments and recommendations for changes to the language of the proposed rule. We understand DTSC’s rationale for proposing such a rule, including consistency between sites within the State of California, but believe that this objective can be achieved while still allowing flexibility for consideration of alternate toxicity values where warranted. We believe that DTSC needs to be consistent with U.S. Environmental Protection Agency (EPA) Superfund directive (EPA Office of Solid Waste and Emergency Response Directives [OSWER] Directive: 9285.7-16 [USEPA 1993]; and 9285.7-53 [USEPA 2003]) on the selection of toxicity criteria; toxicity values should be selected based on

Feeds  
comments  
below

consideration of quality characteristics such as transparency of the assessment, level of peer review, and use of established methodology consistent with current best scientific information and practices.

## SPECIFIC COMMENTS

1. **Revise the rule to clearly describe the process for updating Appendix I, including expert peer review and public review.** The proposed rule presents selected California Office of Environmental Health Hazard Assessment (OEHHA) toxicity criteria (i.e., those included in Appendix I to the proposed rule) as the first tier in the hierarchy. The rule is not transparent as to why certain OEHHA values were selected while others were not and also does not lay out the process for updates to reflect new science and assessments by EPA, OEHHA, and others.

The Issue Memo and the Initial Statement of Reasons (ISOR) document indicate that OEHHA values were selected for Appendix I where those values have undergone public peer-review in their development to satisfy the goals and scientific integrity sought under Health and Safety Code section 57004 and either (1) the OEHHA oral cancer and non-cancer values are at least three times more stringent (considered the threshold for determination of “significance”) than the corresponding Integrated Risk Information System (IRIS) value or (2) the OEHHA inhalation cancer and non-cancer values are more stringent than the IRIS value. However, it does not appear that the thresholds were strictly applied. Furthermore, the use of these measures of significance assumes that a more conservative value is more appropriate, even where the scientific weight of evidence might support the use of a less conservative value. The approach also discounts site-specific considerations. The basis for setting the thresholds of significance is not provided and neither is the reason for using a different threshold for oral vs. inhalation toxicity values. It is recommended that, at a minimum, footnotes be added to Appendix I explicitly listing the procedure for selecting Appendix I values.

At the August 2017 public workshops, DTSC mentioned that Appendix I will be updated regularly, as an amendment to the rule, when there is any new, significant development on toxicity criteria. This could include updating values, adding new chemicals, or dropping chemicals from the list. DTSC stated that amendments of this kind can take between 6–12 months. DTSC also stated that it will use its internal peer review process to make amendments to Appendix I and that there will not be a public review process.

The proposed rule should be revised to describe the process for the initial selection of values for inclusion and for updating Appendix I, which should include a public

review process. The Environmental Council of States (ECOS; 2007 white paper) states that the toxicity value characteristics that should be considered, such as transparency of the assessment, level of peer review, and use of established methodology consistent with current best scientific information and practices. Neither the hierarchy (i.e., the source) of the toxicity value, nor the stringency of the value are listed as sufficient criteria for selection of toxicity values for use in a site-specific risk assessment. The revised rule should be clear as to what types of developments would be considered significant to prompt potential revisions to Appendix I and clearly state the process for conducting regular updates to avoid forcing the use of outdated toxicity criteria, especially given that updates to Appendix I could take several months. The public should have the opportunity to comment on these revisions to further promote transparency and allow for stakeholder input.

INTG-01,  
INTG-02

The rule should also be revised to add language specifying the procedure for establishing toxicity criteria for the interim period where a value based on better quality science has been identified but not yet incorporated into an updated Appendix I.

- 2. Revise the rule to ensure that the highest-quality toxicity value can be used, even if outdated values are available via OEHHA or EPA's IRIS.** The proposed rule appears to preclude proposing alternate toxicity criteria when criteria are available under the first two tiers (OEHHA and IRIS) in the hierarchy, regardless of whether those values truly represent the best science. This approach allows no flexibility in cases where new science is available. In addition, the rule as written may conflict with existing statutory requirements, such as Health & Safety Code §116365(c)(1) which requires that risk assessments to "be prepared using the *most current* principles, practices, and methods used by public health professionals who are experienced practitioners in the fields of epidemiology, risk assessment and toxicology." (emphasis added).

INTG-03

The revised rule should be amended to include a statement that allows for consideration of alternate toxicity values based on site-specific considerations, the confidence and/or certainty in the toxicity value, or the availability of new toxicity information and/or data evaluation techniques to avoid delays in decision-making on sites or moving forward with decisions without use of the best science.

INTG-04

- 3. Revise the rule to explicitly require the use of established guidelines for toxicity value selection.** The process for selecting toxicity criteria under the last tier in the hierarchy (i.e., when an OEHHA and IRIS value are not available) is not specified.

INTG-05

At the August 28, 2017, public workshop, DTSC mentioned that the process will be consistent with recommendations by ECOS (2007). DTSC should also consider the process provided by EPA OSWER (USEPA 2013). Both provide guidelines for evaluating and selecting among available Tier 3 sources (based on timeliness and credibility, level of peer review, use of state-of-the-science methods, etc.). DTSC should consider specifying use of ECOS and EPA guidance or other applicable guidance for selecting toxicity criteria under the last tier to provide more clarity and promote consistent decision-making. In any event, DTSC should make clear that any potential Tier 3 value that is not intended to be applied as a cleanup goal should not be used as such. For example, PPRTV appendix screening values are considered highly uncertain and of low quality; the use of such values as cleanup goals would be inconsistent with EPA Regional guidance and with EPA's Information Quality Guidelines.

INTG-05  
(cont.)

- 4. Clarify how DTSC will approve toxicity criteria for sites for which it is not the lead agency.** The proposed rule seems to imply that DTSC will be the sole approver of toxicity criteria (i.e., lead on risk assessment) for all sites in California, regardless of the designated lead agency, state or federal, for a site. Specifically, the process for selecting toxicity criteria under the last tier of the hierarchy, where approval "by the Supervising Toxicologist, of the Department's Human and Ecological Risk Office, or his or her designee" implies this role for DTSC.

INTG-06

At the August 2017 public workshops, DTSC mentioned that it cannot make rules for other agencies. However, this contradicts the stated goal of this rule, which, as stated in the ISOR, is to create an applicable or relevant and appropriate requirement (ARAR) to be applied to all future cleanups, regardless of the lead agency, thereby removing the decision-making authority from non-DTSC lead agencies. The rule should be revised to clarify the role of both responsible parties and non-DTSC lead agencies in establishing cleanup goals, especially under the final tier in the hierarchy. Specifically, the toxicity criteria selected pursuant to 69021 (c) should not be applied at an EPA or other agency led site without the consent of the EPA or another lead agency. EPA and many other California state agencies indeed have the expertise and resources to evaluate the robustness of the source of the toxicity criteria and identify the "best available science." Moreover, even if the source represents the "best available science," it still may not be robust enough, and should not be applied to thwart legitimate, environmentally protective objectives of the lead agency such as the timely and cost effective cleanup of contaminated sites.

- 5. Revise the rule to reinforce the long-standing practice recommended in EPA's Risk Assessment Guidance for Superfund (RAGS) that toxicity values match the**

INTG-07

**exposure duration of concern.** At the August 28, 2017 public workshop, DTSC mentioned that the rule ONLY applies to chronic exposures and that acute, sub-chronic exposures, or alternate exposure scenarios are not part of the rule-making. DTSC indicated that, if a site has non-chronic exposures, then appropriate non-chronic toxicity criteria can be used (e.g., 8-hr reference exposure levels). However, the rule is not clear in this respect. Other than a footnote in Appendix I, the basis of the toxicity criteria is not mentioned anywhere in the rule and needs to be explicitly stated. Toxicity criteria should match the exposure duration of concern, consistent with RAGS.

INTG-07  
(cont.)

6. **Revise the rule to explicitly state that the toxicity value selection requirements will ONLY be applied prospectively and not retrospectively at sites.** ISOR document indicates the proposed rule includes a statement that “prior remedial decisions will not automatically change once this regulation is effective” and “the rule does not change prior agreements or decisions.” The ISOR also stated:

INTG-08

Participants at the Department’s December 12, 2016 workshop were concerned that the workshop version of the rule would automatically re-open past final remediation decisions at sites. To address this concern, the Department added the explicit provision that the proposed rule is not retroactive. In addition, because this proposed rule is designed to formally adopt present practice, the Department does not anticipate that any past site decisions would be subject to different toxicity criteria under this rule.

INTG-09

However, this specific text does not appear in the proposed rule; instead, proposed Section 69020, Subdivision (b), states:

This Chapter adopts toxicity criteria for all 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 this Chapter.

and

This Chapter does not replace applicable Maximum Contaminant Levels (MCLs) established under Health and Safety Code section 116365 or Title 42 United States Code section 300g as remediation goals.

This is a potentially confusing discrepancy. At the August 2017 public workshops, DTSC stated that the rule will apply ONLY prospectively and not retrospectively. The rule needs to be revised to be consistent with the statement above from the ISOR, which states that “this rule is not retroactive and does not change any prior determination upon its effective date by operation of law.”

7. **Revise the rule to clarify how it applies within the context of 5-year reviews.**

The ISOR states:

Where remediation actions left hazardous substances in place at levels not acceptable for unrestricted (residential or sensitive) use, those remedies at State and Federal Superfund sites undergo a mandatory five-year review for protectiveness. In those cases, the process would include review and update of toxicity criteria as one aspect of the protectiveness determination.

However, this language is not in the proposed rule, but the ISOR under Section 69020, Subdivision (d): “Specifies that this rule does not change existing or historical practice for toxicity criteria selection; the rule does not change prior agreements or decisions.” This language is confusing in its application to the 5-year review process and needs to be made clear and consistent.

Consistent with the ISOR’s statement that the proposed rule is not intended or anticipated to change any existing cleanup goals, the proposed rule should be revised to make clear that DTSC does not intend that it be formally applied as an ARAR in the 5-year review process.

INTG-10

## **SUMMARY OF RECOMMENDATIONS**

The proposed language is very rigid and does not reflect current practices, or EPA directives, which allow reasonable flexibility in risk-management decision-making and setting toxicity values. It is well-established practice for alternate site-specific toxicity values to be employed, but the current language would not allow such flexibility without a complicated, extended, easily challenged, and expensive waiver process. The rule is also unclear in several other aspects, including its applicability to sites where a decision document is in place and also where DTSC is not the lead agency.

The following changes are recommended for the proposed rule:

- Specify the process for updating Appendix I; recommend including a public review process for such changes and a procedure for establishing toxicity criteria for the interim period where a value based on better quality science has been identified but not yet incorporated into an updated Appendix I.
- Clarify whether any flexibility in setting toxicity values will be allowed and the process for such an approach. Include more specificity in the process for selecting toxicity criteria under the third tier of the hierarchy (i.e., where values are not available from Appendix I or IRIS).
- Clarify that the rule is intended to be applied prospectively, not retrospectively.
- Clarify that, because the rule is not intended or anticipated to change any existing cleanup goals, the rule should not be considered as an ARAR in any subsequent Superfund 5-year review processes.
- Develop implementation guidelines so that other state and local agencies will have a clear understanding of how to implement the rule.
- Clearly state the role of responsible parties and non-DTSC lead agencies in selection of a third tier toxicity criteria and the process for engagement.
- Clearly state that toxicity criteria under this rule only apply to chronic exposures and that alternate toxicity criteria can be used for non-chronic exposure scenarios in the screening and remedial cleanup development.

Thank you for the opportunity to provide input to the rule-making process. If you have questions regarding these comments, please contact Ms. DeShields at (707) 636-3222 or Dr. Anderson at (830) 751-2434.

Sincerely,



Bridgette DeShields  
Principal



Janet Anderson, Ph.D., DABT  
Consultant

## REFERENCES

ECOS. 2007. Identification and selection of toxicity values/criteria for CERCLA and hazardous waste site risk assessments in the absence of IRIS values. Environmental Council of the States-DoD Sustainability Work Group, Washington, DC.

USEPA. 1993. Use of IRIS values in Superfund risk assessment. OSWER Directive 9285.7-16. U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response, Washington, DC.

USEPA. 2003. Human health toxicity values in Superfund risk assessments. OSWER Directive 9285.7-53. U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response, Washington, DC.

USEPA. 2013. Tier 3 toxicity value white paper. OSWER 9285.7-86. U.S. Environmental Protection Agency, Regional Tier 3 Toxicity Value Workgroup, OSWER Human Health Regional Risk Assessors Forum, Washington, DC.

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September 20, 2017

Mr. Kevin Depies  
Department of Toxic Substances Control  
8800 Cal Center Drive  
Sacramento, CA 95826

Re: Proposed Toxicity Criteria Rule, OAL No. Z-2017-0725-08

Dear Mr. Depies:

Please accept the following comments regarding the Department of Toxic Substance Control's ("DTSC") proposed rule regarding toxicity criteria for human health risk assessments, screening levels, and remediation goals. Everyone can support environmental regulation that is transparent, consistent, and reasonable. The current text of the proposed rule, however, may not further any of those goals.

The proposed rule fails to provide any guidance or framework whatsoever for how criteria developed by the Office of Environmental Health Hazard Assessment ("OEHHA") in Appendix I would be modified, added, or removed. Far from enhancing predictability, DTSC is essentially omitting any intelligible principle that the Supervising Toxicologist must follow in altering the values listed in Appendix I. The proposed rule should specify how and why the Appendix can be altered, and affirm the public's right to review and comment on proposed changes. The Issue Memorandum seems to contemplate that revisions of Appendix I would constitute rulemaking, but offers no details.

L&W-01

Similarly, the language of the proposed rule offers little guidance as to how the Supervising Toxicologist should approve toxicity values under Section 69021(c). The lack of a framework could easily lead to perverse—and foreseeable—results. For instance, the proposed rule lists a number of potential sources of toxicity criteria, including a Peer-Review Provisional Appendix Screening Toxicity Value. Yet these values are highly uncertain and, by their express terms, are not intended to be applied directly to develop cleanup goals, which is exactly what could happen under the proposed rule if the Supervising Toxicologist selects such a value. Additionally, there is little preventing the Supervising Toxicologist from unnecessarily choosing a more stringent value based on older or less certain science under Section 69021(c) despite the existence of a more reasonable number based on better science. The rule should be revised to ensure that such abuses of discretion cannot occur.

L&W-02

L&W-03

There remain substantial questions about the proposed rule's potential application to established cleanups. Although the Initial Statement of Reasons argues that proposed Section 69020(b) indicates that "this rule is not retroactive and does not change *any* prior determination upon its effective date by operation of law" (emphasis added), that subdivision states only that the rule will "not replace applicable Maximum Contaminant Levels (MCLs) established . . . as remediation goals." Of course, many sites have remediation goals based on values other than MCLs. As written, this very well could have the effect of upsetting established remediation goals at hundreds of existing sites. The proposed rule should state that it does not apply to sites for which a Record of Decision or equivalent document selecting a remedy has already been issued.

L&W-04

DTSC intends that the proposed rule be an Applicable or Relevant and Appropriate Requirement ("ARAR") prospectively, yet fails to clarify how it would be treated in a Superfund Five-Year Review. The rule should be revised to preclude its application as a newly promulgated ARAR in the Five-Year Review process, which would be in accordance with DTSC's stated anticipation that *no* "past site decisions would be subject to different toxicity criteria under this rule."

L&W-05

Thank you for the opportunity to comment on the proposed rule.

Very truly yours,



Benjamin D. Gibson  
of LATHAM & WATKINS LLP



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September 20, 2017

Department of Toxics Substances Control  
8800 Cal Center Drive  
Sacramento, CA 95826  
Attention: Mr. Kevin Depies  
Via Email: [Kevin.Depies@dtsc.ca.gov](mailto:Kevin.Depies@dtsc.ca.gov)

**RE: DTSC Proposed Draft Toxicity Criteria Regulation & Impacts on Cities  
Letter of Concern**

Dear Mr. Depies:

On behalf of the League of California Cities (League), we appreciate consideration of our comments relative to the Department of Toxic Substances Control’s (DTSC) draft Toxicity Criteria regulation for Human Health Risk-Based Screening Levels, Action Levels and Remediation Goals under the California Code of Regulations Division 4.5, Environmental Health Standards for the Management of Hazardous Waste (Regulation).

The League of California Cities has reviewed the Department of Toxic Substances Control’s (DTSC) proposed regulations establishing toxicity criteria for human health risk-based site cleanups. We remain concerned about the potential impact of this rulemaking on the ongoing work to remediate and revitalize former brownfield properties. The many benefits of brownfields projects are well documented in the form of new jobs, increased local economic opportunities, increased revenues for community-benefit projects, improved environmental quality and improved quality of life for our residents.

We are writing to notify you that the new language in the proposed regulations does not satisfy the concerns we expressed in January about DTSC’s informal proposal. While we can appreciate DTSC’s interest and need to ensure cleanup standards are sufficiently protective of human health and the environment, we are concerned the current approach may not be associated with the best available site-specific considerations that could result in increased costs, further delays, decreased property values for the site and surrounding area.

LCC-01

We can appreciate the agency’s proposal to substitute default toxicity screening values for site-specific considerations and require their use in establishing screening levels, however we remain concerned that the regulations apply broadly to all sites and assume the most sensitive future land use.

LCC-02

Many of the remediation and site cleanup projects that would be affected by this proposal already take many years to complete, resulting in negative consequences for our cities in terms of property values, blight, and community health outcomes.

LCC-03

Although the League recognizes that the appropriate state agencies should have the responsibility to perform technical evaluations for site assessment and remediation plans, standing League policy dictates that the clean-up level of a project should be based on its proposed use (i.e., parking garage, as opposed to residential development). We are concerned that the proposed regulatory changes will do more harm than good to critical clean-up projects.

LCC-03  
(cont.)

Of the various concerns with this proposal, its impact on proper brownfield remediation and related economic development projects will be detrimental to community revitalization efforts. The League and various advocates for local economic development have been focused on encouraging revitalization and better use of abandoned properties to the benefit of local environmental and economic conditions. This is particularly true in disadvantaged communities, as defined by CalEnviroScreen, where state and local resources can be effectively leveraged.

DTSC is certainly best qualified to determine remediation processes and levels. We question, however, whether the requirement to use the most stringent toxicity criteria in every situation as contemplated in this proposal is the best approach. Doing so would limit the Department's (and cities') ability to assess the risk associated with a particular site based on the site-specific conditions and adjust cleanup levels and requirements based on those site-specific considerations.

LCC-04

Therefore, we request that DTSC revise the proposed language to ensure that interested parties are allowed the flexibility to obtain clean-up approvals based on site-specific information and final proposed use of the site.

On behalf of the League of California Cities, we strongly urge the Department to maintain flexibility for site-specific decision-making, particularly for its final proposed use, to help avoid significant delays in remediation projects and decreased economic activity. We appreciate your consideration.

We look forward to working with you and the Department further on this matter.

Sincerely,



Erin Evans-Fudem  
Legislative Representative  
League of California Cities



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***Submitted Via Electronic Mail to: [ToxCriteriaRule@dtsc.ca.gov](mailto:ToxCriteriaRule@dtsc.ca.gov)***

September 20, 2017

Mr. Kevin Depies  
Department of Toxic Substances Control  
8800 Cal Center Drive  
Sacramento, California 95826

***RE: Toxicity Criteria Regulations (R-2016-08)***

Dear Mr. Depies,

Materion Brush Inc. ("Materion") submits these comments on the California Department of Toxic Substances Control proposed rule No. 31-Z California Regulatory Notice Register 2017-08-04 pp. 1175-1181(August 4, 2017)( the "Proposal"). These comments demonstrate that the department has relied upon overly conservative application of uncertainty factors in determining an oral reference dose for beryllium and beryllium compounds, potentially leading to unnecessary costs when applied to site remediation. Accordingly, the proposal should be withdrawn or revised.

### **Background**

Materion Brush Inc.'s (Materion) interest in drinking water standards and associated oral toxicity reference values for beryllium is not surprising. Materion is the only fully integrated supplier of beryllium, beryllium alloys and beryllia ceramic in the world. Since its founding in 1931, Materion has concentrated its operations on advancing the unique performance capabilities and applications of beryllium-based materials. Beryllium is a unique material exhibiting physical and mechanical properties unmatched by any other metal. It is one of the lightest structural materials known, yet has specific stiffness six times greater than steel. It possesses high heat absorbing capability and has dimensional stability over a wide range of temperatures. Equipment used in fields such as medicine, aerospace, national defense, computers and telecommunications all rely on beryllium-containing materials. Materion's research efforts are a testament to its belief that standards for exposure to beryllium should be protective of human health and

the environment. However, being heavily engaged in such research, Materion is sensitive to the adverse consequences of risk-based standards that are set well below levels necessary for such protection.

### Comment

**1. California EPA uses overly conservative layers of uncertainty factors resulting in an oral reference dose and public health goal which provides little value for making risk-management decisions and increases cost.**

MAT-01

Note, all the text below pertain to this single comment

California EPA derives in its document entitled *Public Health Goals for Chemicals in Drinking Water, Beryllium and Beryllium Compounds (California EPA OEHHA, September 2003)* an oral reference dose and public health goal from the same studies and data used by US EPA to derive the federal oral reference dose and maximum contaminate level.

The stringency of these drinking water standards for beryllium (both the MCL and PHG) is startling in light of the statement in the 1998 IRIS beryllium health assessment that *"No human information on the oral toxicity of this compound was located"* and the statement on page 21 the 2003 CalEPA Beryllium PHG document *"No reports documenting human beryllium poisoning following exposure to beryllium or beryllium compounds by the oral route have been identified."* There is, of course, an adequate amount of data on human oral exposure to beryllium, as beryllium is found in soil and is commonly found in foods and water supplies. See, for example, the ATSDR Toxicological Profile for Beryllium (containing representative beryllium concentrations in water, soil and food) and the Draft ASTDR Toxicological Profile for Beryllium (September 2000). These reports cite concentrations of dissolved beryllium in groundwater at 352 of 504 sites in the United States at an average concentration of 13.6 µg/l and in 85 of 504 surface water sites in the United States at an average concentration of 23.8 µg/l. CalEPA itself on page 6 its 2003 Beryllium PHG document cites several drinking water surveys documenting drinking water concentrations at or exceeding the PHG of 1 µg/l.

Indeed, such exposure has occurred since the origin of the human species. Against this exposure data, the lack of oral toxicity evidence in humans speaks volumes, yet this point is ignored in computing the MCL and PHG for beryllium. This approach is not only scientifically near-sighted but perverse, as the resulting drinking water standard leads to trivial reductions within water supplies and unnecessary remediation undertaken at significant costs.

The stringency of the drinking water standard and reference dose (RfD) for beryllium arises not only from selective use of data from animal studies, but also the multiplier effect of a series of uncertainty factors. In setting the PHG for beryllium, CalEPA used a composite uncertainty factor of 1,000 to modify the no observed adverse effects level (NOAEL) and determine the Oral RfD. US EPA had used a composite uncertainty factor of 300 in determining its beryllium MCL. It is not entirely clear what basis CalEPA used to justify a more than 3X increase in uncertainty when both standards are based on the same data from the same study.

The assigning of arbitrary uncertainty factors is simply not science and it is important to remember that the word “extrapolation” means “beyond the evidence.” In fact, on September 12, 2011, a scientific peer review panel convened by the USEPA to evaluate the draft, Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies Extrapolation, recommended that the USEPA continue its efforts to encourage risk assessors to use scientific data rather than automatic presumptions as they estimate the level of a chemical that is not likely to harm health.<sup>1</sup>

Absent the use of uncertainty factors in deriving the PHG, the beryllium PHG would be nearly three order of magnitude difference --- based conservatively on a NOAEL from a study which used soluble salts of beryllium<sup>2</sup>. To Materion’s knowledge, these soluble salts don’t frequently exist in commerce. The forms sold and used in industry and found in nature – insoluble forms such as beryllium oxide, beryllium hydroxide, and metallic beryllium—are much less likely to be absorbed into the body and may pose an even lower risk upon exposure.

To conclude, contrary to CalEPA DTSC’s position that there will be no or minimal costs incurred by the private sector from this action, assigning primacy to CalEPA’s more stringent toxicity values (which are more stringent only because they use a larger uncertainty factor and not because they rely on better or more toxicological data) will result in additional remediation and additional costs to not only the private sector but also the government when undertaking remediation within the state of California.

Sincerely,



Troy A. Kajfasz, P.E.  
Director of Environmental Affairs  
Materion Brush Inc.

<sup>1</sup> Rizzuto, P., BNA Daily Environment Report 09/13/2011

<sup>2</sup> *Toxicological Review of Beryllium and Compounds*, EPA/635/R-98/008, U.S. EPA 1998.

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**San Francisco Bay Regional Water Quality Control Board**

**TO:** Kim Gettmann, Department of Toxics Substances Control  
[Kimberly.Gettmann@dtsc.ca.gov](mailto:Kimberly.Gettmann@dtsc.ca.gov)  
Richard Hume, Department of Toxics Substances Control  
[Richard.Hume@dtsc.ca.gov](mailto:Richard.Hume@dtsc.ca.gov)

**FROM:** Ross Steenson  
[Ross.Steenson@waterboards.ca.gov](mailto:Ross.Steenson@waterboards.ca.gov) or 510-622-2445

**CC:** Terry Seward, Stephen Hill, Cheryl Prowell, Nicole Fry, Steve McMasters

**DATE:** September 20, 2017

**SUBJECT:** Review of Proposed Toxicity Criteria Regulation

We reviewed the August 2017 proposed toxicity criteria regulation and associated documents because the regulation will potentially affect the way we manage our sites and the guidance we commonly use in managing our sites. Our comments are as follows:

**1. Proposed Regulation, Section 69021, subdivision (b) (page 3 of 4)**

For those chemicals where OEHHA toxicity criteria are available, but are not selected or identified in Appendix I (e.g., benzo[a]pyrene oral slope factor), we encourage the Department to include a brief technical justification to accompany Appendix I. This would explain the Department's decision and promote improved understanding, transparency, and acceptance of the regulation.

RWQCB-01

**2. Proposed Regulation, Section 69021, subdivision (c) (page 3 of 4) and Initial Statement of Reasons, Section 69021, subdivision (c), second paragraph of section (p. 15 of 25)**

We suggest removing the phrase “(excluding TPH PPRTVs).” The first sentence of subdivision (c) allows flexibility in choosing from other sources of toxicity criteria. Excluding the TPH Fraction PPRTV<sup>1</sup> values without providing an alternative source of TPH toxicity criteria has the potential to mistakenly indicate TPH mixtures have no toxicity and are not of concern. If the Department intends to exclude the TPH PPRTV, identify an alternative source(s) of TPH toxicity criteria.

RWQCB-02

Background for our request

Subsequent to the withdrawal of DTSC's June 16, 2009, *Interim Guidance: Evaluating Human Health Risks from Total Petroleum Hydrocarbons*, our Environmental Screening Levels (ESLs) have employed the USEPA PPRTV noncancer toxicity values for the TPH

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<sup>1</sup> USEPA. 2009. Final Provisional Peer-Reviewed Toxicity Values for Complex Mixtures of Aliphatic and Aromatic Hydrocarbons. Superfund Health Risk Technical Support Center, National Center for Environmental Assessment, Office of Research and Development, Cincinnati, OH. September 30.

fractions in a weighted-average toxicity value approach (February 2016, ESL User's Guide, Appendix F). This allows us to calculate TPH mixture screening levels (e.g., TPH-diesel), which are a tool for managing our cases. At this time, these toxicity values are the best technically justified option for the TPH fractions within the ESL toxicity criteria hierarchy (ESL User's Guide Chapter 3), as neither OEHHA nor USEPA IRIS provide values.

**3. Issue Memo, Related Federal, State, or Local Requirements, first bullet of section, p. 5 of 8**

Modify the language to remove the phrase "Because Water Boards do not have toxicologists, they would rely on OEHHA or DTSC expertise and." The Water Boards have the toxicological expertise necessary for everyday management of our contaminated sites although the Water Boards do not have a toxicologist group which is a result of traditionally not having been able to utilize the toxicologist classifications. We recognize that in some situations some Water Boards work closely with OEHHA or DTSC regarding risk assessment review. It is our understanding that Steve McMasters of the State Water Resources Control Board made a similar comment via email to the Department on August 7, 2017.

RWQCB-03

**4. Issue Memo, Enforcement Mechanism, last sentence of section, p. 8 of 8**

Based on our telephone conversation on September 20, 2017, we recommend the language be modified. We suggest the replacing the existing last sentence with "Because the Department and the Water Boards both oversee Brownfields sites, the Department plans to coordinate with the Water Boards to ensure use of appropriate toxicity criteria consistent with the regulation."

RWQCB-04

We appreciate the Department of Toxic Substances Control's efforts in establishing consistent toxicity criteria statewide. We support statewide consistency on toxicity criteria and are willing to work with the Department to improve this regulation. Please contact me if you would like to discuss these comments and suggestions.

From the Desk of Scott Simpson  
2750 Orange St  
Riverside, CA 92501

September 1, 2017

Mr. Kevin Depies

Department of Toxic Substances Control

8800 Cal Center Drive

Sacramento, CA 95826

Comments on:

DTSC Rulemaking Ref No. R-2016-08 establishing Toxicity Criteria for Risk Assessments, Screening Levels, and Remediation Goals.

Dear Mr. Depies,

Nothing I am suggesting in my comments is contrary to the laws you are implementing and cite in your draft proposal. To adopt these comments into your rule making is not inconsistent with the legal mandate to use best science to effectuate cleanups nor is it in conflict with State or Federal law. My comments if implemented would place DTSC vastly closer to meeting the requirements of law in California. Adopting these comments would decrease the number and frequency of public challenges to DTSC cleanups. Courts would rule in support of cleanup standards at every site. DTSC would feel relief from the constant "Crisis Management" atmosphere that has always plagued DTSC upper management. The previous 40 years of "constant continuous Crisis" ate up DTSC resources

From the Desk of Scott Simpson  
2750 Orange St  
Riverside, CA 92501

leaving management to choose the most convenient low cost option "Dilution into the Environment" by leaving hazardous substances in place justified by a less than one in a million cancer risk assessment. I hope you will give these suggestions serious and thoughtful review.

I am retired. My career has been in state service starting with the University of California Riverside, Statewide Air Pollution Research Center. I went on to employment with the California Department of Food & Agriculture, Pesticide Registration Division, Environmental Hazards Assessment Program, later to become OEHHA. In 1985, I joined the Department of Health Services, Toxics Program, later to become DTSC. In 1996, I took the position of Vice President and Director of Regulatory Affairs with Norris Environmental Services, later to become U.S. Filter Recovery Services. While at the Dept. of Food and Agriculture, in 1981 I received a Unit Commendation award from Governor Brown. At DTSC I received letters of appreciation from the Director and the DTSC recognized my RCRA Enforcement Branch as overall the highest performing of the four branches. While at Norris Environmental Services, I was recognized for receiving our RCRA Part B permit in less than 3 years with no public opposition (unheard of in California) for a one million gallon per day RCRA treat and disposal facility.

Your Problem Statement should be restated to:

"Due to some challenges to the DTSC's methodology and practice of determining how much of a regulated toxic material may be left uncontained (in place) at cleanup sites, the DTSC is promulgating these new rules to provide greater protection of Human Health, Safety and the Environment."

SSIM-01

Restating the objective allows for a better understanding by the general public of the intent and effect upon them of these new rules, however good, flawed or misguided your draft may be. This leads us to a broader discussion of the State of California's responsibility to its public and the environment as delegated to Cal EPA, DTSC and other agencies in law.

Leaving a cleanup site with residual contamination from a release of hazardous substances rather than using the DTSC's authorities and powers to treat or remove the hazardous substance to Non-detect (ND) has been a point of great contention since the inception of California's Toxics Program in the Department of Health Services circa 1975. How clean is clean? This continues to be the question from the public these past 40 yrs. Moving forward, making progress and learning from mistakes is to be recognized but, not yet applauded as, DTSC continues to make the same mistakes over and over (as evidenced by the content of the draft rulemaking package). DTSC pursues the path of least resistance. They use the veil of "Best Science" to set site by site cleanup levels purely favoring cost reduction. That strategy is a continuing mistake that violates Public Policy and provides insufficient public benefit and does not protect the environment. DTSC must reset its focus to a higher level of cleanup standard/goal when implementing the established statutes and regulations of RCRA, CERCLA, HWCL, State Superfund and CLRRRA with respect to **the California Constitution**.

The first California Constitution (circa 1851) including today's version contains some language that is very relevant and important to all the programs under Cal EPA. All DTSC employees are required by law to take the "Oath of Office" swearing to uphold and protect both constitutions. Yet, they are not required to read the California Constitution. I will paraphrase from the constitution.

*The water resources of the state of California, both above ground and below ground, belong to the people of California. The State is the "Caretaker" of the water resources and is charged with 1) improving the quality of the waters of the state and 2) making more water available to the people for their use and enjoyment.*

All of my comments are based upon these words from our state constitution and DTSC must perform all of its duties of managing hazardous substances in furtherance of this Constitutional directive (DTSC is the State and local government is an extension of the state). If DTSC programs are designed to prevent releases to environmental media, remove, treat or confine releases of

SSIM-02

hazardous substances in landfills, then DTSC must also do so at cleanup sites to improve and protect the quality of the waters of the State and thus Public Health and the Environment. DTSC must remember that, they regulate and are thus responsible for improving and maintaining the Hazardous Waste Management Industry which has suffered and declined over the decades due to DTSC decisions to leave waste in place. Funding and more work at cleanup sites, makes them financially competitive and healthier. Leaving some portion of Hazardous Materials unconfined, in place, leaves a threat to health and the environment behind. As long as you can measure it above ND it is a threat to water quality regardless of a Health Risk Assessment finding. At a minimum DTSC must do no harm to the Waters of the State. This is also stated in the Porter Cologne Water Quality Act that established the State policy calling for "Non-degradation of Water Quality." The State (through all its Depts. In Cal EPA) must do so and "make more water available for the people to use" by cleaning contaminated soil and water to ND. A spill of a hazardous substance to water degrades the water quality. To perform a partial cleanup leaving some portion of the hazardous substance in the environment is violating both the state constitution and the PCWQA. Only by pursuing ND as the cleanup standard for most hazardous substances can DTSC meet the Constitutional standard. DTSC can no longer leave contaminated groundwater in place with monitoring of the dilution effect over protracted periods of time. The water must be cleaned to ND at each site.

With respect to soil contamination, the same rule applies because it has been shown at numerous sites that most contaminants move through the environment toward one or more source waters diluting along the way (your risk assessment is a non-sequitur). The water resources of the State belong to the people, not the State. The people hold property rights to the waters of the state. The DTSC does not have discretion on this issue. ND is the limit set by the best available science to implement the law! Citing any Federal authority allowing less than ND as a cleanup standard is irrelevant in California. We can be and are more stringent in our rulemaking.

SSIM-02  
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page)

Following that statement with the Federal version of why California has to set ND in soil and water as the cleanup standard for most Hazardous substances is Public Policy set by Congress in passing into law RCRA, CERCLA and the Clean Water Act (circa 1970). Congress stated that, "Dilution is not the solution to the nations' pollution problem." This has been a critical decision element in many Federal pollution court cases. Federal Courts have ruled that the release of a hazardous substance into an environmental media is dilution. The concentration numbers obtained from soil or water samples at a spill site are lower than what was in the substance before the spill by act of dilution into the environmental media (soil/water). The court further stated that, the act of a release to soil or water is dilution into the environmental media (a man-made chemical and act of release) to be cleaned up to ND regardless of cost. To leave contaminants at a cleanup site is a residual threat to Water Quality, the Environment and Public Health.

To make rules allowing hazardous substances to be left diluted in an environmental media such as soil or water is embracing "**Dilution**" as the solution to the cost of cleanup. That kind of thinking and justifying the setting of cleanup standards at less than ND violates Federal Public Policy and is in conflict with the State Constitution and law in California. We must no longer follow the cost driven rationale for leaving hazardous materials in the environment. It is unlawful and wrong to do so in California.

Now "One rule does not fit all situations" therefore, the DTSC needs an option for cleanup sites where technical and physical limitations would mean a never ending expense to achieve ND cleanup levels. On a site by site basis, DTSC can only ask the Court of appropriate jurisdiction, to review each case. The DTSC would be suing the People of the State of California as owners of the water resource at risk. Using best science, you should also ask the court to accept confinement strategies to contain the hazard in place with monitoring (impermeable cap and GW treatment/monitoring).

So, this rulemaking should be withdrawn and revised adopting the legal rational of justifying the ND standard for most of the regulated substances in a new

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revised DTSC rulemaking package. DTSC may deviate only where the elements or compounds regulated are also found in the local environment at the site (background). The regulated metals being the easiest to recognize in this category, DTSC should have levels for cleanup set at the natural background for all metals, other regulated substances would have cleanup levels set at ND.

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How do we deal with the high cost of cleanup? After 40 years of struggling to resolve this question, it is time for DTSC to find a way to pay for cleanup where public funding is necessary to clean the site. I have a few suggestions. 1) Cal EPA could establish an Environmental Fee of one per cent on all purchases collected in the same manner and time as the sales tax is collected. All retail transactions subject to the Sales Tax have a general environmental cost associated with the manufacture, import, transportation, sale and use of products. A fee is not a tax if the payer benefits from the service provided by the fee. In this scenario, the service is "The Protection of and Restoration of the States' Water Quality" to preindustrial/agricultural levels (1851). This would be a direct service to the water resources owned by the people paying the fee. I am confident this fee would generate hundreds of millions of dollars annually. If you can do this then, Cal EPA should dissolve all existing industry fees except permit application fees and manifest fees. 2) Cal EPA could seek legislation to expand the existing Lottery statute to authorize lottery games to fund cleanup of polluted water and soils threatening water quality. This allows the Public lottery participants to decide they want lottery funds to go to these purposes by choosing to play an Environmental lotto game. 3) Set up a Go Fund Me page for each site DTSC is working on eligible for tax deduction status. Market this effort to private and corporate donors who wish to assist impacted communities with cleanup of private properties near known sites. This could also be an Alternative Environmental project funded by enforcement cases. 4) If all fails, put forth a sales tax increase proposal to the legislature. A secure source of public funding resolves other issues that have plagued DTSC decision making. Public funding tends to have stability and predictability for budgeting priorities. Public funds can be leveraged by bonding a portion of the income flow and a given projects' land.

SSIM-03

From the Desk of Scott Simpson  
2750 Orange St  
Riverside, CA 92501

Funding is tricky and difficult and my suggestions reflect that, in the end, the public always pays through higher housing costs, transportation costs, food costs and, really everything we buy in commerce. So, let go of many of the individual industry fees and collect a small fee on every taxable transaction (including real estate). These ideas would not interfere with DTSCs cited authority to make Responsible Parties pay for cleanup costs. The new funds and stability could cover fixed costs of the DTSC by removing these expenses from Cost recovery on CLRRRA cleanups and other activities seeking cost recovery for staff time).

SSIM-03  
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Nothing I have suggested in my comments is contrary to the laws you are implementing and cite in your draft proposal. To adopt these comments into your rule making is not inconsistent with the legal mandate to use best science to effectuate cleanups. Our best science determines ND for each contaminate and how to clean it up.

My comments if implemented would place DTSC vastly closer to meeting the requirements of law in California. The public and the environment would benefit from ND cleanups improving the public's water quality and the public funds the majority of the cost. Also, I don't mean to imply that the funding should be solely for the use of the DTSC.

Sincerely,

Scott Simpson

Board Member Friends of the Riverside Hills

Board Member Reform Riverside

Member CCAEJ

**From:** Stone, Linda@Waterboards  
**To:** [toxcrieriareule](#)  
**Subject:** Comments on Toxicity Criteria Rule  
**Date:** Thursday, September 21, 2017 7:53:08 AM

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- 1) Please clarify whether the adoption of the Toxicity Criteria Regulations will result in risk-based remediation goals that are lower than remediation goals that are based on a maximum contaminant levels (MCLs) for drinking water. If so, please clarify whether the responsible party will be required to demonstrate to the Department of Toxic Substances Control that it is technologically or economically infeasible to achieve risk-based remediation goals and that the alternative remediation goals that is remediation goals greater than risk-based remediation goals are technologically and economically achievable.
- 2) Please clarify whether the toxicity criteria listed under CCR, title 22, section 6901, subdivision (b) will be routinely reviewed and revised as new scientific information becomes available.

STO-01

STO-02



Innovative solutions  
Sound science

September 19, 2017

Kevin Deples  
Attn: Toxicity Criteria Rule  
Department of Toxic Substances Control  
8800 Cal Center Drive  
Sacramento, California 95826

**SUBJECT:** Rule to Establish Toxicity Criteria for Risk Assessments, Screening Levels, and Remediation Goals

Dear Mr. Deples:

We appreciate this opportunity to provide comments regarding the proposed rule intended to establish toxicity criteria for application to risk assessments, screening levels, and remedial goals. ToxStrategies, Inc., is a multidisciplinary scientific consulting firm that strives to develop innovative solutions to address the scientific, technical, and regulatory challenges surrounding the effects of chemicals on human health, whether they are found in the environment, foods, or pharmaceuticals. Our staff of toxicologists and other scientists have decades of experience using toxicology data and toxicity criteria for health risk assessment.

We agree that California toxicity criteria should be considered in CERCLA risk assessments conducted in California. We also agree with the goals of consistency and transparency with regard to the use of toxicity criteria in risk evaluations conducted for sites in California, and we understand the issue created if federal sites in California are held to different standards. However, we find that the proposed rule, in its current form, could introduce restrictions that would hamper the use of the best available science in risk assessments. With that preface, we offer the following comments on the proposed regulation to be added to Title 22, Division 4.5 of the California Code of Regulations.

### **Regulation vs. Guidance**

As the federal government and other state agencies have recognized, setting cleanup standards or toxicity criteria in regulation or law is problematic, because the state of the science changes at a more rapid pace than the process of revising regulations and laws. As an alternative to regulation by law, guidance documents have been used as the point of reference, because the level of effort to change guidance documents is much lower. We understand that California is promulgating this regulation so that California-specific toxicity criteria are considered applicable, relevant, and appropriate requirements

} TS-1

(ARARs) under CERCLA. However, this goal could be achieved by referencing a database or providing a mechanism for updating California-specific criteria outside the formal regulatory process. This would allow for greater flexibility, as science evolves, to generate new guidance and toxicity values. This approach should be considered in this proposed regulation, in the same way that the Environmental Protection Agency's (EPA's) Integrated Risk Information System (IRIS) or provisional peer-reviewed toxicity values (PPRTVs) are referenced in the regulation. For example, rather than referencing specific values for criteria published by California's Office of Environmental Health Hazard Assessment (OEHHA), the regulation should direct the reader to specific sources for those values (e.g., OEHHA's toxicity criteria database), as it does for the non-California sources in Section 69021 (b). If the intent of the proposed rule is to focus on a specific list of chemicals for which OEHHA believes their criteria are more health-protective than federal standards, then the list of chemicals could be specified in the regulation and a reference made to where and how those toxicity criteria are available in state guidance documents or websites. Rigid adherence to what may become outdated toxicity criteria could delay implementation of health-protective cleanup levels or incur unnecessary costs for remediation in cases where toxicity criteria are refined and demonstrate that a chemical is less toxic.

TS-01  
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### Use of "Diversity"

Use of the premise of California's diversity as a basis for this rulemaking is inappropriate. This concept is used twice in Section 69020 of the proposed regulation ("California's diverse demographics" and "California's diverse population"). California's diversity is an important factor in many respects, but not with regard to toxicity criteria for human health effects as the science is currently practiced. In fact, in most cases, toxicity criteria are based on animal toxicology data, and the diversity of the California population is not a consideration. In cases where unique characteristics of a group of people make them more susceptible to an adverse effect, they are typically referred to as "sensitive subpopulations." The example for tetrachloroethylene (PCE) provided in the Initial Statement of Reasons,<sup>1</sup> and other subgroups such as children, the elderly, pregnant women, etc., are considered when data are available to support focusing on these groups rather than the general population. Additionally, while California is more diverse than other places in the United States, it is not the only place with these specific subpopulations, and EPA is obligated to consider these subgroups in their development of toxicity criteria as well. Using the term "diversity" in the text of the regulation mischaracterizes the predominant reason for the differences between federal and California's state criteria, which is technical interpretation of the underlying scientific data. To suggest otherwise, and to use inappropriately a term that carries such political weight, should be avoided in a state rulemaking. Using the term inaccurately in

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<sup>1</sup> Perhaps the reason that EPA has not adopted the more stringent approach for developing the toxicity criteria for PCE is that they do not agree with the level of conjecture in OEHHA's assessment in the name of protectiveness. OEHHA suggests that there may be a biological variation in the human conjugation rates for PCE's GST [glutathione S-transferase] pathway that accounts for the large spread in the data, but acknowledges they do not know which GSTs are most active in conjugating PCE.

this context lessens the impact that it may have in situations where its use *is* appropriate. A statement consistent with the rationale published in the Initial Statement of Reasons would be more appropriate—to wit, “They [California’s toxicity criteria] afford greater protection of human health, safety, and the environment than the nationwide minimum standard provided by analogous federal toxicity criteria.”

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### Screening Levels vs. Remediation Goals

While the regulation provides a target cancer risk of  $1 \times 10^{-6}$  and hazard quotient of 1 to be used for developing screening levels, it should be stated clearly that the regulation does not intend to require that remediation goals also meet this standard. Screening levels often have been considered as remediation goals, which is not their intended purpose. Language to limit the application of the target risk and hazard indexes in this section to the screening process—rather than simply relying on the distinctions between remediation goals and screening levels presented in the definitions section, would provide better clarity in the regulation.

TS-03

### OEHHA’s Less Conservative Toxicity Criteria

In several cases, the OEHHA value published in Appendix I of the proposed regulation is *less* conservative than the value recommended by EPA in IRIS. If California is obligated to use criteria at least as stringent as EPA, these California toxicity criteria could not be used at federal sites. The specific chemicals and toxicity criteria to which this discrepancy applies are: arsenic (inhalation unit risk [IUR]); cis-, trans-, and 1,3-dichloropropene, vinyl chloride (cancer slope factor [CSF]); and epichlorohydrin and manganese (non-diet) (reference exposure level [REL]).

TS-04

### Conclusion

It seems unfortunate to limit the ability of the State of California to use the best available science when new information becomes available to assess human health risks. Additionally, it would be more productive to engage technical experts to resolve the inconsistencies between federal and California’s toxicity criteria on a chemical-by-chemical basis, rather than inappropriately using California’s diversity as the rationale for adhering to California’s toxicity criteria.

Kevin Deples  
September 19, 2017

ToxStrategies

Thank you for the opportunity to provide comments on this regulation, which affects us and all citizens of California.

Sincerely,



Ann H. Verwiel  
Senior Managing Scientist



Gregory P. Brorby, DABT  
Practice Leader



Deborah Proctor  
Managing Principal Scientist