

# STATE OF CALIFORNIA

## INITIAL STATEMENT OF REASONS RULE ESTABLISHING TOXICITY CRITERIA FOR RISK ASSESSMENTS, SCREENING LEVELS AND REMEDIATION GOALS

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## INTRODUCTION

The proposed regulation would add new provisions to Title 22, Division 4.5, as new Chapters 50 (section 68400.5) and 51 (sections 69020-69022), set a narrative cleanup performance standard, and adopt the toxicity criteria listed in Appendix I for use in all human health risk assessments calculating risk-based<sup>1</sup> screening levels and risk-based remediation goals at hazardous substance release cleanup sites in California. Because this rule includes a corrective action regulatory section that points to and requires compliance with the State Superfund risk assessment regulation sections proposed here, all analysis for sections 69020-22 applies to the function of the corrective action regulatory section because it requires use of and compliance with sections 69020-69022.

## PROBLEM STATEMENT

The California Department of Toxic Substances Control (Department) is promulgating this (new) rule to adopt Office of Environmental Health Hazard Assessment<sup>2</sup> (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 clarification to achieve California's more stringent protections had not been necessary as the Department had, until recently, successfully resolved potential conflicts over toxicity criteria under existing state and federal law and guidance, without specifying the values in a regulation. More recently, however, the U.S. Air Force (Air Force) began to insist on using the substantially less stringent federal Integrated Risk Information System (IRIS) toxicity criteria for perchloroethylene (PCE, also known as tetrachloroethylene) and other contaminants for cleanups in California. This is contrary to the Department and U.S. Environmental Protection Agency (U.S. EPA) Region 9's long-standing (i.e., decades) practice of using California toxicity criteria at hazardous substance release sites in California, when state toxicity criteria are more protective than federal criteria.

This rule formalizes the Department's existing practice developed with U.S. EPA Region 9's concurrence, and as required and authorized under the California Hazardous Waste Control Law (HWCL, Health and Safety Code sections 25100 et seq., also commonly referred to as Chapter 6.5), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, 42 U.S.C. 9601 et seq.), and the California

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<sup>1</sup> In this document, risk-based means based on both human health risk for cancer and risk for an adverse non-carcinogenic health effect.

<sup>2</sup> The California Environmental Protection Agency (CalEPA) is the cabinet level agency that oversees and coordinates the activities of the Department, OEHHA, Department of Pesticide Regulations, Department of Resources Recycling and Recovery, State Water Resources Control Board, and the Air Resources Board.

Hazardous Substances Account Act (“State Superfund”, Health and Safety Code section 25300 et seq., also commonly referred to as Chapter 6.8)<sup>3</sup>, to better protect California’s most susceptible people among its various populations, consistent with state law and federal law and guidance. These specified toxicity criteria would also apply to risk assessments under the California Land Reuse and Revitalization Act (CLRRA, Health and Safety Code sections 25395.60-25395.119) which uses Chapter 6.8 standards for response actions, including risk assessments. The Department believes this regulation will not only clarify and improve certainty, but may also limit controversy and significantly reduce staff time spent debating toxicity criteria choices on private and publicly owned sites by specifying the requisite level of protection for cleanups at hazardous substance release sites in California.

## **PURPOSE**

The Department proposes to add the following sections to Title 22 of the California Code of Regulations at the following section numbers, consistent with the locations of prior related regulations (now repealed):

Section 68400.5: To clarify that risk assessments under the Hazardous Waste Control Law use the toxicity criteria and comply with narrative performance standard in sections 69020-69022.

Section 69020, subdivision (a): To note explicitly two laws that provide context for this regulation: California Environmental Protection Agency’s (CalEPA’s) statutory obligation to conduct its public health and environmental protection programs to achieve environmental justice, and the OEHHA duties to assist and coordinate within CalEPA to pursue the protection of children who are more susceptible to environmental hazards.

Section 69020, subdivision (b): To explain why an enhanced level of protection using OEHHA toxicity criteria, rather than the federal default IRIS values for contaminants listed in Appendix I, achieves the desired level of protection in California.

Section 69020, subdivision (c): To note the cleanup laws to which these toxicity criteria will apply.

Section 69020, subdivision (d): To provide the Department’s intent to establish ARARs that will apply prospectively to all sites statewide, including, but not limited to federal sites, and that prior remedial decisions will not automatically change once this regulation is effective. Specifies that this rule does not change existing or historical practice for toxicity criteria selection; the rule does not change prior agreements or decisions; nor does the rule apply to replace maximum contaminant levels (MCLs)

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<sup>3</sup> The California Regional Water Quality Control Boards also oversee cleanup of hazardous substance release sites under Chapter 6.8 as well as under separate Water Code authority. The Water Board cleanups under Chapter 6.8 are subject to this regulation. Where toxicity criteria are an issue, Water Board relies on OEHHA, and also on the Department in some cases.

established for drinking water.

Section 69020, subdivision (e): To provide definitions for terms used in this regulation.

Section 69021, subdivisions (a) and (b): To set forth the sequence from (a) to (c) for selection of toxicity criteria used in risk assessments and in the calculation of screening levels and remediation goals. Subdivision (a) specifies that values for the contaminants listed in Appendix I must be used for the contaminant released to the environmental medium (soil, water, or indoor air) at issue. If no value(s) are listed for that contaminant in Appendix I, then the listed toxicity criteria in IRIS must be used, as listed in subdivision (b).

Section 69021, subdivision (c): If no value is in Appendix I or IRIS, then the sources in subdivision (c) may be used upon approval from the Department. Proposed and ultimately approved toxicity values must be consistent with Health and Safety Code section 25356.1.5 which incorporates best scientific methods and practices, federal law and guidance. Sources for toxicity criteria used in present practice include OEHHA values with no IRIS counterpart that the U.S. EPA Regional Screening Levels (RSLs) use, U.S. EPA Provisional Peer Reviewed Toxicity Values (PPRTVs), the Agency for Toxic Substances and Disease Registry (ATSDR) Minimal Risk Levels, PPRTV Appendix Screening Toxicity Values, and U.S. EPA Superfund Health Effects Assessment Summary Table values.

Section 69022, subdivisions (a): To set and define the narrative standard for (human health) risk-based protection as one that uses the toxicity criteria required under section 69021.

Section 69022, subdivision (b): To define the screening level.

Section 69022, subdivision (c): To confirm that selection of risk-based remediation goals will continue to follow the National Oil and Hazardous Substance Pollution Contingency Plan (NCP), consistent with existing practice under Health and Safety Code section 25356.1.5, subdivision (b); and “not inconsistent,” pursuant to Health and Safety Code section 25357.5, subdivision (b), with the NCP.

## **NECESSITY**

Risk assessors, and regulatory oversight agencies like the Department and U.S. EPA, use toxicity criteria to calculate human health risk and hazard, risk-based screening levels, and risk-based remediation goals when evaluating sites with hazardous substance releases<sup>4</sup> and determining the actions necessary to protect human health

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<sup>4</sup> The definition of release has already been promulgated at 22 CCR 66260.10, and is essentially the same as Health and Safety Code section 25320, as restricted by HSC section 25321. The definition in

and the environment. In California, the Department oversees, conducts, and confers with federal, state, and local agencies who oversee and conduct remediation, or cleanup, and mitigation of hazardous substance<sup>5</sup> releases to the environment statewide under the HWCL, and state and federal Superfund laws. Oversight agencies and persons conducting this cleanup work and oversight do so using federal and state statutes, regulation and guidance documents.

Section 121 of CERCLA explicitly authorizes the state to apply requirements more stringent than federal levels.<sup>6</sup> The California HWCL is more stringent than, broader in scope than, and authorized to operate in California in lieu of the federal Resource Conservation and Recovery Act (RCRA, 42 U.S.C. 6901, et seq.).<sup>7</sup> Furthermore,

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Section 66260.10 says:

“Release” means:

(a) Any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment.

(b) “Release” does not include any of the following:

(1) Any release which results in exposure to persons solely within a workplace, with respect to a claim such exposed persons may assert against their employer.

(2) Emissions from the engine exhaust of a motor vehicle, rolling stock, aircraft, vessel or pipeline pumping station engine.

(3) Release of source, byproduct, or special nuclear material from a nuclear incident, as those terms are defined in the Atomic Energy Act of 1954 (42 U.S.C. 2011, et seq.), if such release is subject to requirements with respect to financial protection established by the Nuclear Regulatory Commission under section 2210 of Title 42 of the United States Code or, for the purposes of section 104 of the federal act (42 U.S.C. 9604) or any other response action, any release of source byproduct, or special nuclear material from any processing site designated under section 7912(a)(1) or 7942(a) of Title 42 of the United States Code, which sections are a part of the Uranium Mill Tailings Radiation Control Act of 1978.

<sup>5</sup> Hazardous wastes and their constituents are subsets of Hazardous substances by statutory definition under HSC 25316.

<sup>6</sup> Superfund Section 121(d)(2)(A)(ii) which states (emphasis in bold added):

With respect to any hazardous substance, pollutant or contaminant that will remain onsite, if...

(ii) **any promulgated standard, requirement, criteria, or limitation under a State environmental or facility siting law that is more stringent than any Federal standard, requirement, criteria, or limitation**, including each such State standard, requirement, criteria, or limitation contained in a program approved, authorized or delegated by the Administrator under a statute cited in subparagraph (A), and that has been identified to the President by the State in a timely manner, **is legally applicable to the hazardous substance or pollutant or contaminant concerned or is relevant and appropriate under the circumstances of the release or threatened release of such hazardous substance or pollutant or contaminant, the remedial action selected** under section 104 or secured under section 106 **shall require, at the completion of the remedial action, a level or standard of control for such hazardous substance or pollutant or contaminant which at least attains such legally applicable or relevant and appropriate standard, requirement, criteria, or limitation.**

<sup>7</sup> Section 3006 of RCRA allows US EPA to authorize state programs to operate in lieu of RCRA. Department’s authorizations are published in the federal register at 57 Fed.Reg. 32726-02 (1992) and 66

because hazardous wastes are a subset of hazardous substances under Health and Safety Code section 25316, the term “releases of hazardous substances” includes the release of almost all hazardous wastes. The major exception to this is the petroleum exclusion under both state and federal Superfund laws.

Since at least 1994, the Department has used a combination of OEHHA and IRIS toxicity criteria to address the cleanup of various contaminants at release sites statewide, consistent with its constitutional police powers to protect human health, safety and the environment, and its statutory mandate to use best science not inconsistent with federal law and guidance under Health and Safety Code sections 25356.1.5 and 25357.5.

Toxicity criteria are numerical values that convey a hazardous substance’s dose-response relationship for potential carcinogenic risk or adverse and non-carcinogenic harmful health effects (i.e., hazard). Toxicity criteria are contaminant-specific, do not factor in exposure assumptions, and are not site-specific. Human health risk assessments use toxicity criteria in standardized equations to estimate the potential excess cancer and non-cancer health impacts from exposure to hazardous substances. Potential cancer impacts are calculated as the probability, or risk, of additional cancer occurrence; this risk is compared to a threshold of one in a million. Potential non-cancer impacts are calculated in comparison to a safe exposure level for the contaminant of potential concern and represented by a hazard quotient. If the hazard quotient is greater than one, there is a potential for increased non-cancer health effects, while a hazard quotient less than one indicates that adverse non-cancer health effects are not likely to occur. The U.S. EPA Regional Screening Levels website [U.S. EPA, <https://www.epa.gov/risk/regional-screening-levels-rsls>], discusses how toxicity criteria are used to develop risk-based screening levels including “to determine if potentially significant levels of contamination are present at levels warranting further investigation” and/or remediation. In addition, where promulgated cleanup levels are not available, or are not deemed adequately protective, risk assessors must develop health-protective cleanup levels using available toxicity criteria.

Scientists develop toxicity criteria values through the analysis of data from the scientific literature consisting of empirical studies (i.e., typically animal-based, or, if available, epidemiological), and publish their conclusions and values in peer reviewed publicly available databases. Human health risk assessors then use these toxicity criteria in their risk assessments to estimate the potential excess cancer risk or non-cancer hazard effects from exposure to these contaminants of concern.

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Fed.Reg. 49118-01 (2001). Health and Safety Code section 25159.5 reflects this authorization in subdivision (a) where it states:

(a) In adopting or revising standards and regulations pursuant to this chapter, the department shall, insofar as practicable, make the standards and regulations conform with corresponding regulations adopted by the Environmental Protection Agency pursuant to the federal act. This section does not prohibit the department from adopting standards and regulations that are more stringent or more extensive than federal regulations.

In reviewing risk calculations and site-specific cleanup documents to decide what, if any, additional work is necessary to address the human health risk and potential hazard from the contaminant(s) at a site, regulatory agencies compare the contaminant concentrations found to numerical screening levels. These screening levels include the U.S. EPA RSLs or the Department's screening levels discussed in the Department's Human Health Risk Assessment (HHRA) Note 3. Several U.S. EPA RSLs use the OEHHA toxicity criteria. Screening levels are calculated using the contaminant's toxicity criteria and default (not site-specific factors) exposure assumptions (e.g., exposure frequency, exposure duration, exposure time and averaging time).

The California OEHHA and the U.S. EPA Office of Research and Development (ORD) have developed toxicity criteria for various contaminants, but not necessarily for the same contaminants. Federally developed and peer-reviewed toxicity criteria are in the IRIS database (available online). ORD develops these federal toxicity criteria or values to assure the nationwide, minimum standard of protection across all 50 states, while OEHHA can be more stringent and tailored for California's legislated policy directives. One such California legislative mandate is the risk assessment provision in the State Superfund law itself. Health and Safety Code section 25356.1.5(b) requires risk assessments to include:

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

A second legislated mandate is the Children's Environmental Health Protection Act (Senate Bill No. 25, Escutia, chaptered 1999, 1998-99 Reg. Sess.) which focuses on the special vulnerabilities of children to environmental hazards, and requires specialized attention to children's health in risk assessments. OEHHA's standard practice is to account for the potential increased sensitivity to exposures early-in-life (during pregnancy), and during infancy, childhood, and the elder years. OEHHA also incorporates assumptions or modeling parameters better suited to and more inclusive of California's diverse demographic, as with PCE discussed more fully below.

OEHHA's approach is consistent with a third legislative mandate in Public Resource Code section 71110. That section directs the CalEPA, OEHHA and the Department's parent agency) to develop standards, programs, and protections; and enforce its programs and protections in a manner that promotes environmental justice. The purpose is to ensure equity and afford fair treatment, accessibility, and protection for all persons, regardless of race, culture, and income level. As a result, OEHHA's toxicity criteria differ from their federal ORD counterparts for many hazardous substances found at release sites in California.

OEHHA had previously developed screening levels pursuant to Health and 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 ...”<sup>8</sup>, 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.

OEHHA develops its toxicity criteria using a transparent, scientifically supported and high quality peer-review process that solicits, incorporates and addresses public and professional comments. U.S. EPA ORD uses a similar peer-review process for the IRIS Program. The OEHHA toxicity criteria have been consistently used within the State of California by its boards, departments and offices, and by U.S. EPA Region 9 for hazardous substance release sites to screen and develop remediation goals since at least 1994.

In this regulation, the Department is expressly continuing its past practice by adopting and mandating use of OEHHA’s scientifically supported, peer-reviewed toxicity criteria (listed in Appendix I) for the reasons discussed in more detail below. This level of protection is consistent with California’s environmental policy and legal obligation to protect its people from the harmful effects of hazardous substances released to the environment.

The overarching reasons for drafting this rule, as proposed, are to: 1) enhance the clarity, predictability, and enforceability of these requirements; 2) to cover all hazardous substance release sites as CERCLA does; 3) to be at least as protective as federal law; and 4) by doing all of the above, to qualify these requirements as ARARs for application to hazardous substance release sites that are federally owned or subject to federal oversight.

**Section 68400.5:** Because the HWCL and State Superfund laws have different chapters of regulations associated with them, insertion of this section provides notice that risk assessors addressing cleanup under the HWCL (corrective action sites) must use the toxicity criteria and narrative performance standard in sections 69020-69022. Because hazardous waste is a subset of hazardous substances whose releases can be addressed under either law, this makes clear that the toxicity criteria specified under Sections 69020-69022 apply to both. Consistency across these two laws also further supports the state position that these provisions are ARARs as noted below.

**Section 69020, subdivisions (a) and (b):** Subdivision (a) provides the background and subdivision (b) provides the purpose for the rule as it clarifies how to carry out or comply with Health and Safety Code section 25356.1.5. In contrast to most California regulations, this subdivision provides more detail behind California’s adoption of

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<sup>8</sup> <https://oehha.ca.gov/risk-assessment/california-human-health-screening-levels-chhsls>

OEHHA toxicity criteria over the default IRIS values based on California's diverse population and the legislative mandates to assure the fair treatment of all people in the implementation and enforcement of environmental laws (environmental justice) under Public Resources Code, section 71110, and the Children's Environmental Health Act mentioned above, when selecting toxicity criteria to substantively control the screening levels and remediation goals for cleanup of hazardous substance releases.

Subdivision (a) explains that differences in culture, genetics and age can contribute to different exposures and sensitivities to contaminants. OEHHA's standard practice when establishing toxicity criteria accounts for genetic diversity among individuals in their modeling parameters. Additionally, their toxicity criteria further protect those with increased sensitivity to exposures at various stages, including early-in-life (during pregnancy), infancy, childhood, and the elder years. In this way, the OEHHA toxicity criteria are better suited to and more inclusive of California's diverse demographic, and more protective than federal law as expressly contemplated by section 121 of CERCLA (42, U.S. Code section 9621), and consistent with Chapter 6.8 and HSC section 25356.1.5(b)(4).

Subdivision (b) states that the purpose of the regulation is to adopt the toxicity criteria as substantive standards of control, and to provide inclusive health-based protection for California's diverse population, of all ages, including the most sensitive receptors, and better achieves the fair treatment of all people with respect to implementation and enforcement of environmental cleanup laws referenced in Public Resources Code section 71110 above.

### PCE Example

The scientific literature shows that between ethnic populations, there is a significant degree of genetic variation or genetic polymorphism in the enzymatic steps of the glutathione-conjugation pathway, one of two pathways that metabolize PCE. This genetic variation causes a substantive difference in the way some ethnic sub-populations metabolize PCE. As a result, some ethnic groups experience greater adverse health effects when exposed to the same dose of PCE. California has a very demographically diverse population. To protect all ethnic subpopulations and groups equally, it is necessary to consider the genetically-driven variations in PCE metabolism and response when establishing toxicity criteria.

OEHHA's PCE inhalation unit risk factor (air pathway) incorporates both the glutathione and oxidative metabolic pathways, whereas the federal IRIS value only uses the oxidative pathway. In 2015, according to the Henry J. Kaiser Family Foundation, the population of California consisted of 39% White, 6% Black, 38% Hispanic, 15% Asian, 2% two or more races, and 1% Pacific Islander (<http://kff.org/other/state-indicator/distribution-by-raceethnicity/?currentTimeframe=0&sortModel={%22colId%22:%22Location%22,%22sort%22:%22asc%22}>). Using both metabolic pathways, OEHHA factors this diversity into its PCE toxicity criteria which makes the OEHHA PCE inhalation unit risk appropriate to protect

California's ethnically diverse population.

As discussed in the September 2016 OEHHA Air Toxics Hot Spots Program, *Perchloroethylene Inhalation Cancer Unit Risk Factor, Technical Support Document for Cancer Potency Factors, Appendix B* (emphasis in bold added):

“...although there are unresolved issues related to the Chiu and Ginsberg (2011) model predictions for PCE's GST pathway...a large part of the spread in estimated human conjugation rates may be **due to biologic variation in the human population**. Three important classes of GST enzyme have been identified in human liver cytosol: GSTA, GSTM, and GSTT. Both GSTM and GSTT have isoforms, GSTM-1 and GSTT-1, that are absent in a relatively large fraction of the population as a result of genetic variation (in this case due to gene deletion). Moyer *et al.* (2007) investigated the prevalence of GSTM-1 and GSTT-1 null individuals in the population and found frequencies of 50.5 - 78%, and 33.5 - 73.5%, respectively. Ginsberg *et al.* (2009) reported that some ethnic groups have high percentages of members that are null in both the GSTM-1 and GSTT-1 isoforms. **For example, more than 30% of ethnic Chinese people appear to lack both enzymes**. It is currently not known which GSTs are most active in conjugating PCE. However, it appears that some low molecular weight halogenated hydrocarbons, such as dichloromethane, are primarily conjugated by GSTT-1. If PCE is a substrate mainly of GSTT-1 or GSTM-1, then **the presence of many individuals lacking these enzymes would produce a large range of variability in the rate of PCE conjugation.**”

In addition, the Department's toxicologists have written and submitted a detailed review of the genetic variation in the enzymes responsible for PCE metabolism, titled *Review: Risk Assessment Implications of Variation in Susceptibility to Perchloroethylene Due to Genetic Diversity, Ethnicity, Age, Gender, Diet and Pharmaceuticals*. The journal article is accepted for publication by the official journal of the Association for Environmental Health and Sciences Foundation, the *Human and Ecological Risk Assessment: An International Journal* (2017 – In Press).

As this PCE example demonstrates, adoption and use of the Appendix I criteria for screening level and remediation goal calculations are necessary to protect California's different subpopulations.

For clarity, this subdivision also notes that this regulation, and any risk-based levels that result, do not replace applicable Maximum Contaminant Levels (MCLs), established under Health and Safety Code section 116365, in cleanup decision making. This also eliminates confusion on whether to do risk assessment calculations where doing so would be pointless because a drinking water standard already exists and would be applied. These limitations are consistent with the Department's intent, practice, and also with the above-listed state and federal laws to keep this rule focused on the use of toxicity criteria for making human health based decisions for hazardous substance

release cleanup sites.

Section 69020, subdivision (b) also states the regulation's scope and identifies its applicability to all hazardous substance release sites. The Department is applying this rule to all sites for which it has cleanup and rulemaking authority, and those are the hazardous substance release sites for which it conducts or oversees hazardous substance (including hazardous waste) cleanup under the HWCL (also known as corrective action), the State Superfund statutes (Chapter 6.8) and CERCLA sites. The Department notes that this rule will also govern work under CLRRRA, because section 25395.94 of CLRRRA explicitly requires risk assessments to be prepared in accordance with subdivisions (b), (c) and (d) of Health and Safety Code section 25356.1.5; which this rule clarifies and makes more specific. Also, involvement of the supervising toxicologist as described in 69021 subdivision (c) provides consistency across sites because criteria in this third tier must meet with management approval, and aligns application of this rule with CERCLA practice.

It is the Department's intent to be consistent with existing practice for all hazardous waste and hazardous substance cleanup sites statewide. Under the NCP, and as noted below, an ARAR must be a promulgated rule of general application to the same kinds of sites and contaminants as on federally-owned or overseen properties. This rule mandates that the Appendix I toxicity criteria apply statewide, so that it will also qualify to apply to cleanups at federally owned or overseen sites. Failure to apply this rule at federal sites would result in potentially greater human exposure to contamination than currently allowed, and less stringent toxicity criteria, risk-based screening levels, and risk-based remediation goals compared to other (potentially adjacent) non-federal sites.

This subdivision also includes important limitations to eliminate unnecessary work and uncertainty by preserving the validity of past decisions. This subdivision notes that this rule is not retroactive and does not change any prior determination upon its effective date by operation of law. 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. 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.

**Section 69020, subdivision (c)** provides definitions to prevent confusion and clarify the meaning and application of sections 69021 and 69022.

To align with federal law and guidance, the Remediation Goals definition borrows heavily from the Preamble to the NCP (55 Fed.Reg 8713, March 8, 1990). That Preamble text reads: “Remediation goals are a subset of remedial action objectives and consist of medium-specific or operable unit-specific chemical concentrations that are protective of human health and the environment and serve as goals for the remedial action.”

The Screening Levels (SLs) definition is adapted from U.S. EPA’s Screening Levels FAQ, again in an effort to align state and federal implementation of all guidance for cleanup under the listed laws, while still allowing use of more protective state toxicity values to achieve greater protection of human health in California. The U.S. EPA FAQs at <https://www.epa.gov/risk/regional-screening-levels-frequent-questions-may-2016#FQ1> describes the U.S. EPA SLs in number 1 as follows:

The screening levels (SLs) presented on this site are developed using risk assessment guidance from the EPA Superfund program and can be used for Superfund sites. They are risk-based concentrations derived from standardized equations combining exposure information assumptions with... EPA toxicity data. SLs are considered by the Agency to be protective for humans (including sensitive groups) over a lifetime; however, SLs are not always applicable to a particular site and do not address non-human health endpoints, such as ecological impacts. The SLs contained in the SL table are generic; they are calculated without site-specific information. They may be re-calculated using site-specific data.

The Contaminants of Potential Concern (COPCs) definition is adapted from U.S. EPA’s *A Guide to Preparing Superfund Proposed Plans, Record of Decision, and Other Remedy Selection Decision Documents* (July 1999):

Chemicals of Potential Concern...: those chemicals that are identified as a potential threat to human health or the environment and are evaluated further in the baseline risk assessment.

The Department, OEHHA, and IRIS are defined to avoid confusion.

Total Petroleum Hydrocarbons (TPH) is defined in the Agency for Toxic Substances & Disease Registry (<https://www.atsdr.cdc.gov/ToxProfiles/tp123.pdf>) as: “the measurable amount of petroleum-based hydrocarbon in an environmental medium.”

**Section 69020, subdivision (d):** Out of an abundance of caution for additional helpful context, other undefined terms should be read consistent with the authorizing statutes, and because both Chapters 6.5 and 6.8 can be more stringent than federal law, reference is limited now to those two chapters.

**Section 69021, subdivisions (a) and (b):** Adoption of the Appendix I criteria is necessary to protect human health because of the scientific differences among subpopulations.

This section identifies the sources of toxicity criteria and the order of use in calculating screening levels and remediation goals, and human health risk assessments for hazardous substance release sites in California. Subdivision (a) names the first source, Appendix I, which lists the peer-reviewed OEHHA oral and inhalation cancer and non-cancer toxicity criteria used for evaluating those exposures. The adopted OEHHA toxicity criteria are compiled into a table to provide easy reference, with columns for cancer potency values and non-cancer health-hazard values for the oral and inhalation pathways since different means of exposure (pathways) may have different intensities of effect. For instance, ingesting or eating a toxin can have a more acute or harmful effect than merely touching it. This Appendix lists values that are significantly more protective than, more updated than, or more tailored to California's legislatively mandated protection levels (age, etc.) than their counterpart IRIS values.

By this ordering of sources, the listed OEHHA toxicity criteria supplant or supersede use of their federal counterpart(s) in IRIS for the specific COPC. Periodic amendments of this regulation will be necessary to require use of a newer or updated future IRIS or OEHHA toxicity criteria. For contaminants not listed in Appendix I, available IRIS criteria apply under subdivision (b), consistent with the U.S. EPA's Office of Solid Waste and Emergency Response (OSWER) directives.

If the inhalation pathway is a potential route of exposure and Appendix I, IRIS and the other sources listed in the regulation do not have an inhalation unit risk factor or inhalation reference concentration (RfC), the Department's standing practice is to calculate the

- unit risk factor or RfC using the COPC's oral slope factor or oral reference dose selected under subdivision (a), (b), then (c), and
- the route-to-route extrapolation equation from Appendix B of the U.S. EPA Soil Screening Guidance: Technical Background Document (Second Ed. May 1996).

This rule does not address route-to-route extrapolation, but this regulation also does not change the Department's practice. The Department is examining how best to work toward rulemaking on this aspect of risk assessment.

When conducting a risk assessment, all COPCs must be addressed. The Appendix is neither exclusive nor an exhaustive list of toxicity criteria for contaminants to be evaluated, and absence of the COPC from Appendix I does not eliminate the obligation to sample or calculate screening levels or remediation goals for the COPC in any risk assessment. Any selected toxicity criteria or value used shall be consistent with Health and Safety Code section 25356.1.5, subdivision (c).

The Department also intends that this rule would require use of listed or available toxicity criteria for metallic or metalloid element COPCs that are inorganic soluble salts and oxides of common oxidation states, but would not require use for metallic or metalloid element COPCs, (e.g., alloys), that differ in form from the primary compound on which the toxicity criteria are based. For example, metallic elements may exist in multiple oxidation states, form various organic and inorganic compounds, or be alloyed together with other metal or non-metallic elements, thus resulting in different toxicity than the elemental metals on which the toxicity criteria are based. Metals present at the site that are assumed to be inorganic soluble salts or oxides of common oxidation states, such as hexavalent chromium or lead, are subject to the toxicity criteria set in the regulation.

If no Appendix I or IRIS value exists for the contaminant and pathway, subdivision (c) provides additional sources that must also be consistent with OSWER directives and Health and Safety Code section 25356.1.5, subdivision (c), and which may be used upon approval by a designated representative of the Department.

#### **Section 69021, subdivision (c):**

Toxicity criteria used from sources in section 69022 subdivision (c) must apply best available science, be health-based, and for consistency statewide, are subject to approval by the Supervising Toxicologist, or his or her designee, of the Department's Human and Ecological Risk Office. Duplicate or conflicting toxicity criteria for the same COPC will not exist in both the IRIS and PPRTV databases, because PPRTVs values are removed once they undergo sufficient review and vetting to become an IRIS value. As the scientific portion of this regulation, the listed Appendix I toxicity criteria values the have already undergone public peer-review in their development to satisfy the goals and scientific integrity sought under Health and Safety Code section 57004.

Also, consistent with the Department's long-standing current practice, subdivision (c) excludes the TPH-Mixture PPRTVs from the list of available criteria. The U.S. EPA publishes TPH PPRTVs for complex mixtures (e.g., fractions) of aliphatic and aromatic hydrocarbons. The Department does not use these TPH PPRTVs because of analytical limitations and the potential variability in reporting TPH results. In particular, TPH PPRTV criteria are based on a range of hydrocarbons, and the presently available laboratory methods do not provide the specific quantity of each hydrocarbon or hazardous constituent in each sample.

#### **Section 69022. Screening Levels and Remediation Goals**

Section 69022 sets a narrative cleanup performance standard in subdivision (a) that is the protection afforded by calculating screening and remediation goals using the toxicity criteria specified in section 69021. Adoption of this narrative performance standard is necessary to protect human health because of the susceptibility differences among subpopulations, as described above. This avoids defaulting to protections afforded by

IRIS where scientifically supported and significantly more protective criteria exist in Appendix I, and thereby requires that level of genetically- and culturally-inclusive health-based protection. This “closes the loop” and ensures consistency that protective toxicity criteria are applied at all phases of the cleanup process (e.g., site characterization, contaminant evaluation, and remedy evaluation, development and implementation). This narrative standard in no way prohibits cleanup to levels more protective than the generic or site-specific screening levels calculated using the toxicity criteria required under section 69021.

Subdivision (b) sets screening levels for contaminants at a  $1 \times 10^{-6}$  incremental excess lifetime cancer risk and a hazard quotient of 1 consistent with U.S. EPA RSLs and the Department SLs from prior practice. For consistency with federal law, the Department adopts this level from the U.S.EPA’s *Soil Screening Guidance: User’s Guide*. July 1996 at Page 4, as referenced by RAGS Part A.

For clarity and to ensure consistency with federal law, subdivision (c) specifies that remediation goals developed under this rule will be consistent with the NCP, and in particular with CFR Title 40, section 300.430.

Toxicity criteria are a critical component for setting screening levels which are used early in the site evaluation process. This rule ensures that consistent screening levels are applied at all sites in California. Not having the rule could result in application of less stringent screening levels for military sites compared to private sites, such that action (e.g., further evaluation or possibly remedy implementation) could be required at a private site, but not at an adjacent federal site.

As noted before, the Department seeks to promulgate this rule to qualify it as applicable to federal cleanups. The Department therefore describes below how this rule qualifies as an ARAR.

## **APPLICABLE OR RELEVANT AND APPROPRIATE REQUIREMENTS (ARARS)**

### **States’ Rights and CERCLA ARAR Requirements**

The Department exercises its Constitutional and statutory authorities to protect public health, safety, and welfare by requiring cleanups of hazardous wastes and hazardous substances to use state standards where they protect human health more than federal law requires. The Department achieves this level of protection by using the Appendix I toxicity criteria to determine risk-based screening levels, and remediation goals, which the Department uses to establish acceptable uses for sites with hazardous substances left in place. The HWCL is the more stringent or broader in scope state law authorized by U.S. EPA to govern hazardous waste management and cleanups (also known as “corrective action”) in lieu of RCRA in California. CERCLA also recognizes state authority to be more protective than federal standards by explicitly allowing use of

states' more stringent protections at section 120.

In promulgating this rule, the Department seeks to formally adopt the toxicity criteria presently and historically used in risk assessments for the environmental cleanups that it oversees. Because the purpose and use of toxicity criteria under the listed state laws is to provide more health protection and applies to more COPCs than federal law, both sections 69021(a) and 69022(a) requirements are substantive. Both are enforceable under the respective laws. Since both requirements apply to exactly the kinds of contaminants, releases to environmental media, remediation actions (and any remediation goals calculated to protect human health), and the same kinds of locations and responsible parties<sup>1</sup> that CERCLA actions address, both qualify under CERCLA and the NCP as applicable requirements for federal site cleanups under the NCP's section 300.400(g)(1). When analyzed under the federal rubric for relevant and appropriate requirements under CERCLA, sections 69021(a) and 69022(a) requirements also satisfy all 8 criteria in the NCP's section 300.400(g)(2).

For all of the reasons above, this rule's Use Requirement and Performance Standard Requirements are substantive applicable and relevant and appropriate requirements for all hazardous substance cleanups in California under the HWCL, the State Superfund law and the CERCLA, to the extent that they are more stringent than federal law.

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## **ECONOMIC IMPACT ASSESSMENT/ANALYSIS**

The Department has evaluated the potential economic impact from implementation of the proposed regulations. The evaluation is presented below.

### **Creation or Elimination of Jobs within the State of California**

The proposed regulations clarify and specify the selection of toxicity criteria for human health risk assessments and establishing health-based screening levels and remediation goals at hazardous substance release sites in California. The proposed regulations implement procedures in use since at least 1994 to assess human health risk at hazardous substance release sites in California. On the basis that these past procedures the Department has determined that no jobs in California will be created or eliminated due to the proposed regulations.

### **The Creation of New Businesses or the Elimination of Existing Businesses Within the State of California**

The proposed regulations clarify and specify the selection of toxicity criteria for human health risk assessments and establishing health-based screening levels and remediation goals at hazardous substance release sites in California. The proposed regulations implement procedures currently utilized to assess human health risk at hazardous substance release sites in California. This action does not change the liability of parties responsible for cleanup. Furthermore, this action does not change the screening and cleanup levels presently required at sites in California under Department oversight because it does not change existing practices for evaluating risk and developing risk-based cleanup actions for hazardous substance cleanup sites in California. This rule does not increase cleanup costs or the scale or scope of hazardous substance release cleanups required to date in California.

While not a business, it is worth noting that the U.S. Air Force is the only party that may be directly fiscally impacted by the rule as the Department is engaged in two formal disputes at Edwards Air Force Base over applicable toxicity criteria for PCE and other contaminants. If the Air Force prevails in the disputes, the costs for addressing the contamination at the dispute sites would be reduced by using less stringent toxicity

criteria than required under current practice, memorialized in this rule. However, after the effective date of this rule, the Air Force may choose to settle the dispute and use the OEHHA toxicity criteria, thus saving staff time and costs. It is possible that promulgation could also reduce Department staff time and invoiced costs for staff debating the same issue with other landowners, and pursuing or defending disputes to protect employee and resident health at contaminated properties undergoing cleanup. The Department anticipates approximately four formal disputes with the military by the end of the calendar year, some or all of which could potentially be resolved by implementing this regulation.

As the proposed regulation implements existing practice the Department concludes there will be no or minimal economic impact resulting from implementation. Therefore, the Department has determined that the proposed regulations will not have a significant impact on the creation of new businesses or the elimination of existing businesses in the State of California.

### **The Expansion of Businesses Currently Doing Business Within the State of California**

The proposed regulations clarify and specify the selection of toxicity criteria for human health risk assessments and establishing health-based screening levels and remediation goals at hazardous substance release sites in California. The proposed regulations implement procedures in use since at least 1994 to assess human health risk at hazardous substance release sites in California and does not change the liability of businesses responsible for cleanup of hazardous substances. Based on the observed effects of these past procedures, the Department has determined that the proposed regulations will not have a significant impact on the expansion of businesses currently doing business within the State of California.

### **The Benefits of the Proposed Regulations to the Health and Welfare of California Residents, Worker Safety and the State's Environment**

With implementation of the proposed regulations, the Department has identified the following benefits to the health and welfare of California residents, worker safety and the State's environment:

- 1) Provides more protection than federal toxicity criteria for California's population from hazardous substances in the environment.
- 2) Ensures that human health risk assessments protect the entirety of California's diverse population (age, race, culture, income levels) based on known science and consistent with state environmental justice and child-protection objectives, through adoption of the OEHHA toxicity criteria in Appendix I.

- 3) Defines the protective risk-based screening level as  $1 \times 10^{-6}$  for cancer risk and a hazard quotient of 1 for non-cancer risk for all screening level risk assessments which is consistent with federal guidance.
- 4) Ensures that toxicity criteria used in California are of high scientific quality and credibility, and apply the best available science.
- 5) Ensures consistency by applying these toxicity criteria to risk-based cleanups of all hazardous substances release sites (corrective action and hazardous substance remediation) in California.
- 6) Mandates that risk-based cleanup screening levels and remediation goals (cleanup levels) achieve the same protection at federal hazardous substance cleanup sites as for all other cleanup sites in California.
- 7) Reduces uncertainty and time spent resolving differing interpretations of federal guidance to decide applicable toxicity criteria.

### **EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS**

As above, although the proposed action will directly apply to businesses statewide, including small businesses, the Department concludes that the economic impact, including the ability of California businesses to compete with businesses in other states, will not be significant because this rule does not change existing practices and formalizes the status quo.

### **ALTERNATIVES CONSIDERED**

**Alternative 1** was the version published on November 11, 2016 and discussed in a public workshop on December 12, 2016. This was similar to the proposed regulation, but less descriptive. This workshop version listed the OEHHA, IRIS and PPRTVs as sources of toxicity criteria and specified the use of the “most protective” criteria from these sources. It also required the use of the selected criteria for all risk assessments, and for developing screening levels and remediation goals. That version set screening levels and the point of departure to be  $1 \times 10^{-6}$ , and implied that remediation goals also be set at the same level. This simplified version resulted in misinterpretation and numerous comments/concerns which are addressed in the proposed regulation. The NCP was not specifically referenced in Alternative 1.

**Alternative 2** was based on Alternative 1 with the following differences based on public comments on the “pre-APA” draft regulation:

U.S. EPA PPRTVs became the second source after OEHHA and IRIS values. The

Department does not consider the PPRTVs to be a primary source as they do not undergo the same rigorous peer review and evaluation as IRIS and OEHHA values. In the proposed rule (Alternative 3), the Department made PPRTVs a third-tier source on par with sources other than IRIS and OEHHA.

- A provision excluded metallic elements that are not inorganic soluble salts and not oxides of common oxidation states. For example, metallic elements may exist in multiple oxidation states, form various organic and inorganic compounds, or be alloyed together with other metal or non-metallic elements resulting in different toxicity than the elemental metals on which the toxicity criteria are based. The Department omitted this provision from the proposed rule (Alternative 3) as unnecessary because the listed toxicity criteria value is for a different form of the metal.
- A “variance” provision to allow new IRIS or OEHHA values to be used in place of values in the regulation’s repository after the effective date of this rule, but before it could be amended. This provision was discarded in the proposed rule (Alternative 3) because the variance process was complicated, would be difficult and costly to implement (e.g., the Department anticipated repeated petitions for variances), and potentially be deemed a procedural component that could prevent the rule from applying to federal facility cleanups.
- The text was edited to clarify that the rule was not setting remediation goals at an incremental excess lifetime cancer risk of an individual at  $1 \times 10^{-6}$  and a cumulative hazard index of 1.

**Alternative 3** is the Proposed Rule.

The Department crafted the proposed rule to address the many concerns raised through careful drafting to reflect present practice and clarify the protection required under state law. The proposed rule does not specifically require use of the most protective OEHHA or IRIS toxicity criteria. It adopts OEHHA toxicity criteria in Appendix I as the clearest way to provide notice of the values to use. Toxicity criteria not provided in Appendix I are to be obtained from the IRIS database. If a given contaminant toxicity criteria are not provided in Appendix I or IRIS, then the listed alternative scientifically credible sources are to be used. Please see the Purpose and Necessity sections above for more discussion on the toxicity criteria sources and order of use.

The NCP is referenced in the proposed rule because of numerous concerns expressed regarding loss of discretion to choose remediation goals within the risk management range of  $10^{-4}$  and  $10^{-6}$ . This rule does not replace the NCP in any way, but provides clarity on the limited issue of toxicity criteria for hazardous substance release cleanups in California.

The Department realized that the great number of public comments and requests for

clarification indicated a need for more information on the purposes, applicability and scientific bases for this rule, and therefore included more information in section 69020, including definitions.

Other formatting or ordering changes have been made for ease of reading. Please see the above Purpose and Necessity which fully explain the sections of the proposed rule.

**No Action Alternative.** This does not achieve the objective of promulgating a generally applicable standard for all parties cleaning up sites based on human health risk, and therefore, is not a feasible alternative.

## **EFFORT TO AVOID DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS**

This rule clarifies the toxicity criteria for use in corrective action under the California HWCL which applies in California in lieu of the federal act (RCRA). The Department does not understand this regulation to be necessary to retain authorization to administer the HWCL. As noted above, the HWCL is more stringent and broader in scope than RCRA. If this regulation were, however, necessary to retain the HWCL authorization, Health and Safety Code section 25159 would exempt this regulation from review for nonduplication with respect to corrective action.

Federal hazardous waste corrective action guidance refers readers to CERCLA guidance<sup>9</sup> and RAGS. The CERCLA regulations are the National Oil and Hazardous Substances Pollution Contingency Plan, commonly known as the National Contingency Plan (“NCP”, 40 C.F.R. § 300 et seq.). The NCP refers to risk assessments at 40 C.F.R. section 300.430, subdivision (a)(2) for Remedial Investigation/Feasibility Studies, and under subdivision (d) for Remedial Investigations, among others, but does not specify the required toxicity criteria. As noted above, neither federal nor state toxicity criteria have been adopted by rule or statute to date for use in cleanups of hazardous substance release sites based on human health risk, so adoption of these values does not conflict with federal regulations.

In addition, because the federal levels are a nationwide minimum standard of protection, and CERCLA and the HWCL expressly authorize more stringent state protections than federal law, this rule’s use and adoption of more stringent toxicity values more than meets the federal standard and does not conflict with either federal law. The Department’s policy and practice are to conduct risk assessments and decision making for human health the same way for hazardous waste sites under Chapter 6.5 as for its Chapter 6.8 and CERCLA hazardous substance sites.

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<sup>9</sup> See OSWER directive 9375.6-11 Guidance on Deferral of NPL Listing Determinations While States Oversee Response Actions (<https://nepis.epa.gov/Exe/ZyPDF.cgi/2000L26C.PDF?Dockey=2000L26C.PDF>)

Furthermore, use of section 69021's second and third tier values, IRIS and other databases respectively, is consistent with the federal guidance noted before because IRIS is the nationwide minimum standard and the other sources are routinely used because they are consistent with the best professional judgment noted in the guidance. As noted earlier in the Necessity section, the Department has implemented and followed U.S. EPA guidance for decades, and pursues this rule to formally promulgate a standard that will bind federally-owned undergoing cleanup in the same way as all other California hazardous substance release sites under Department oversight.

Finally, section 69023 sets a narrative standard that is more protective than federal values, applies to the same persons in an enforceable manner, and defines screening level in a manner consistent with federal guidance.

For these reasons, this rule neither duplicates nor conflicts with federal regulations and formally adopts requirements consistent with federal guidance.