

# **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

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## 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.

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

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.

### 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.

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.

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.

## 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.

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.

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.

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.