

TITLE 22

45-DAY PUBLIC NOTICE AND COMMENT PERIOD

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

NOTICE IS HEREBY GIVEN that the Department of Toxic Substances Control (Department) proposes to adopt California Code of Regulations (CCR), Title 22, Division 4.5, sections 68400.5, 69020, 69021, and 69022 to set a narrative cleanup performance standard, and adopt the listed toxicity criteria for all human health risk assessments calculating health-based (hereinafter risk-based) screening levels and risk-based remediation goals at hazardous substance release cleanup sites in California.

PUBLIC WORKSHOPS

The Department will hold public workshops on the proposed regulations at the following times and locations:

NORTHERN CALIFORNIA

Date: August 28, 2017
Time: 2:00 to 4:00 PDT
Location: California Department of Toxic Substances Control
8800 Cal Center Drive
Sacramento, California 95826
Board Room
Webinar Link: <https://video.calepa.ca.gov/>

SOUTHERN CALIFORNIA

Date: August 31, 2017
Time: 2:00 to 4:00 PM PDT
Location: California Department of Toxic Substances Control
5796 Corporate Ave.
Cypress, California 90630
All-Staff Room
Webinar Link: <https://video.calepa.ca.gov/>

At the times and locations listed above, any person(s) may ask questions about the proposed rule in an interactive workshop setting. The workshops will convene at 2:00 PM PDT and will remain open until 4:00 PM PDT, or until attendees have no further questions, whichever occurs first. Attendees are also welcome to attend the Public Hearing (below) to have questions or comments on record.

PUBLIC HEARING

The Department will hold a public hearing on the proposed regulations at the following time and location:

Date: September 20, 2017
Time: 2:00 PM – 4:00 PM PDT
Location: 8800 Cal Center Drive
Sacramento, California 95826
Board Room
Webcast Link: <https://video.calepa.ca.gov/>

At the time and location listed above, any person(s) may present statements or arguments, orally or in writing, relevant to this proposal described in the Informative Digest. The public hearing will convene at 2:00 PM PDT and will remain open until 4:00 PM PDT, or until no attendees present testimony, whichever occurs first.

Representatives of the Department will preside at the hearing. The Department requests persons who wish to speak to please register before the hearing. Pre-hearing registration is conducted at the location of the hearing from 1:00 PM PDT until the hearing commences. Registered persons will be heard in the order of their registration. Anyone else wishing to speak at the hearing will have an opportunity after all registered persons have been heard.

All visitors are required to sign in upon arrival to the Sacramento Department Regional Office at the administration desk on the first floor of the building. Please ask the guard at the security desk for directions. Be sure to allow adequate time to sign in and receive a visitor badge before the public hearing begins.

NOTICE PERTAINING TO ACCESSIBILITY & REASONABLE ACCOMMODATION

All documents related to these regulations can be made available in alternate format (*i.e.*, Braille, large print, etc.) or in another language, as requested, in accordance with State and Federal law. Further, to ensure the public has equal access to all available services and information, the Department will provide disability related reasonable accommodations and/or translator/interpreter needs, upon request. For assistance, please contact the following staff person as soon as possible, preferably no later than 10 business days prior to the scheduled hearing:

Ms. Litiana Patino
Department of Toxic Substances Control
P.O. Box 806
Sacramento, California 95812-0806
Litiana.Patino@dtsc.ca.gov
Phone: (916) 324-3095

TTY/TDD/Speech-to-Speech users may dial “7-1-1” for the California Relay Service.

WRITTEN COMMENT PERIOD

Any interested person(s) or their authorized representative(s) may submit written comments relevant to the proposed regulatory action to the Department in either electronic or hard-copy formats. Written comments will be accepted until 11:59 P.M on September 20, 2017.

Written comments may be submitted electronically through the Department regulations email address at ToxCriteriaRule@dtsc.ca.gov or please direct hard-copy written comments to:

Mr. Kevin Depies
Department of Toxic Substances Control
8800 Cal Center Drive
Sacramento, California 95826
Attn: Toxicity Criteria Rule
E-Mail: ToxCriteriaRule@dtsc.ca.gov
Fax Number: (916) 255-6560

AUTHORITY & REFERENCE

Authority

These regulations are being adopted under the following express authorities:

- Health and Safety Code (HSC) section 25150 stipulates that the Department shall adopt, and revise when appropriate, standards and regulations for the management of hazardous substances;
- HSC section 25159 states that the Department shall adopt and as necessary revise regulations pertaining to the administration of the state hazardous waste program;
- HSC section 25159.5 authorizes the Department to adopt regulations for corrective action;
- HSC section 25351.5 grants the Department authority to adopt any regulations necessary to carry out its responsibilities pursuant to Chapter 6.5;

- HSC section 58004 grants the Department all duties, powers, purposes, responsibilities and jurisdiction of the Toxic Substances Control Program of the State Department of Health Services, including, but not limited to, those powers and duties specified in Chapter 6.5; and
- HSC section 58012. This section allows the Department to adopt and enforce rules and regulations for the carrying out of the Department's duties.

The Department also has implied rulemaking authority under Chapter 6.82, the California Land Reuse and Revitalization Act of 2004 (Health and Safety Code [HSC] sections 25395.60-25395.109). This law designates the Department as an oversight agency at sections 25395.64 and 25395.71, and requires hazardous substance cleanups done under that chapter, including risk assessments, to meet the requirements of Chapter 6.8 (HSC sections 25395.92 and 25395.94). Therefore, the Department has the implied authority to clarify and implement requirements under this law, and should do so consistent with its express authority for rulemaking under Chapter 6.8.

Reference

These regulations implement, interpret, or make specific the following statutes:

- HSC section 25150 authorizes the Department to apply the standards and regulations adopted for the management of hazardous wastes. It also stipulates that the Department may not adopt standards or regulations that are less stringent than that by RCRA and shall inform other state and local agencies of adoption of relevant regulations;
- HSC section 25159 authorizes the state to receive and maintain federal authorization to administer a state hazardous waste program in lieu of the federal program;
- HSC section 25159.7 authorizes the Department to carry out all hazardous waste management responsibilities imposed or authorized by the federal act and the Comprehensive Environmental Response, Compensation, and Liability Act as amended;
- HSC section 25187 authorizes the Department to issue orders for corrective action to address hazardous waste releases to the environment;
- HSC section 25355.8 prohibits the Department from issuing a no further action determination for hazardous waste sites unless certain conditions are met;
- HSC section 25356.1 and 25356.1.5 authorizes the Department to issue a Remedial Action Plan for designated hazardous waste sites and that remedial action be no less stringent than those required under the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), and also allows that state requirements can be more stringent than those under the NCP;
- HSC sections 25395.92 requires property owners to address a hazardous substance release site consistent with Chapter 6.8 protections. Section 25395.94

requires parties to comply with section 25356.1.5, Chapter 6.8's risk assessment provision, for risk assessments;

- HSC section 25159.5 stipulates that state standards and regulations conform with corresponding U.S. Environmental Protection Agency (U.S. EPA) standards and regulations, respectively but also that the state may adopt standards more stringent than U.S. EPA;
- HSC Section 116365 authorizes the State Water Board to adopt primary drinking water standards enforced by the Department which are not being replaced by the proposed regulations; and
- Public Resources Codes section 71110 requires the California Environmental Protection Agency to, among other things, designing its mission for programs and standards to “conduct its programs in a manner that, including minority populations and low-income populations of the state” and “promote enforcement of all health and environmental statutes within its jurisdiction” in the same manner.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Policy Statement Overview

For specified contaminants at hazardous substance release sites, the proposed regulations would require the use of California's Office of Environmental Health Hazard Assessment (OEHHA) toxicity criteria, which take into account California specific considerations, and are more stringent than federal toxicity criteria. Toxicity criteria are used for risk assessments, and setting risk-based screening levels and remediation goals for contaminants at hazardous substance release (e.g., cleanup) sites. The proposed regulations will formalize the long standing current practice dating back to 1994. Finally, the proposed regulations will ensure consistency in selecting the appropriate toxicity criteria for all cleanup sites in California factoring in California's overall environmental goals and environmental justice objectives, across age, racial, ethnic, cultural and income differences.

Proposed Regulations

The proposed regulations will adopt specified California toxicity criteria, for use in human health risk assessments, to set risk-based screening levels and remediation goals, for both corrective action under the Hazardous Waste Control Law (Chapter 6.5) and response actions under the Hazardous Substances Account Act (Chapter 6.8). Note also that because execution of the California Land Reuse and Revitalization Act (Chapter 6.82) specifically refers to Chapter 6.8 for risk assessments; risk assessments, screening levels and remediation goals under Chapter 6.82 will also be governed by this rule.

Anticipated Benefits

The proposed regulation will:

- 1) Provide more protection than federal toxicity criteria for California's population from hazardous substances in the environment;
- 2) Ensure that human health risk assessments protect the entirety of California's diverse population (age, race, culture, and income levels) based on known science and consistent with state environmental justice and children's health-protection goals, through adoption of the OEHHA toxicity criteria in Appendix I;
- 3) Define the protective risk-based screening level as one in a million 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) Ensure that toxicity criteria used in California are of high scientific quality and credibility, and apply the best available science;
- 5) Ensure 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) Mandate 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; and
- 7) Reduce uncertainty and time spent resolving differing interpretations of federal guidance to decide applicable toxicity criteria.

Summary of Existing Statutes and Regulations

The Department has researched existing state statutes and regulations determining toxicity criteria for human health risk evaluations including determining human health screening levels and setting remediation goals. The Department has identified only the following statutes and regulations for evaluating human health risk in California:

- Health and Safety Code section 25356.1.5, subdivision (c). Specifies that human health risk assessments be consistent with the federal National Contingency Plan; include the most current sound scientific methods, knowledge, and practices of public health and environmental professionals; and be based on public health considerations, to the extent scientific data are available;
- Water Code, Division 7, section 13304.2 Water Quality Enforcement and Implementation. Specifies human health risk assessments for "Brownsfield" sites;
- Health and Safety Code, Division 26, section 39660 Identification of Toxic Air

Contaminants. Requires the Air Resources Board to evaluate health risks of certain chemicals emitted to the atmosphere;

- Health and Safety Code, Division 26, section 42315 Air District Permitting for Non-vehicular Air Pollution Control. Requires the Air Resources Board to evaluate health effects of toxic substances released to the atmosphere;
- Health and Safety Code Division 26, section 44300 *et seq.* Air Toxics Hot Spots Program. Requires the Air Resources Board to evaluate human health risk of emissions derived from industrial, commercial, and disposal facilities in California;
- Health and Safety Code, Division 104, Section 116365 California Safe Drinking Water Act. Requires the State Water Board to assess human health risks in adopting drinking water standards; and
- Health and Safety Code, Section 901: Children's Environmental Health Center. Authorizes the Department of Public Health to assess health risks for proposed school sites.

Evaluation of Inconsistency/Incompatibility with Existing State Regulations

The Department has evaluated the proposed regulations for any inconsistency or incompatibility with existing state statutes and regulations. The Department has identified no state regulations specific to toxicity criteria application to human health risk assessments and has determined that the proposed regulations are consistent with the requirements specified in the above state statutes.

Evaluation of Inconsistency/Incompatibility with Existing Federal Regulations

The proposed draft rulemaking is consistent with federal requirements, particularly 40 Code of Federal Regulations Part 264 and especially section 300.430.

Incorporated By Reference

The proposed regulation incorporates by reference the unit risk factor, oral slope factor, reference dose, and reference concentration values in this U.S. EPA IRIS database, available online at <https://www.epa.gov/iris>, as of September 30, 2017.

DISCLOSURE REGARDING THE PROPOSED ACTION

MANDATES ON LOCAL AGENCIES OR SCHOOL DISTRICTS

The Department has determined that the proposed regulations will not impose a mandate on local agencies or school districts.

COST OR SAVINGS TO STATE OR LOCAL AGENCIES, OR SCHOOL DISTRICTS

The proposed regulations will not result in costs to any local agency or school district requiring reimbursement pursuant to Government code sec. 17500 *et seq.*

OTHER NONDISCRETIONARY COST OR SAVINGS ON LOCAL AGENCIES

The Department has determined that there are no other nondiscretionary cost or savings imposed upon local agencies.

COST OR SAVINGS IN FEDERAL FUNDING TO THE STATE

The Department does not anticipate any changes to federal funds which the State of California receives.

COST OR SAVINGS TO ANY STATE AGENCY

The proposed regulations implement procedures that have been historically applied to California hazardous substance release sites. Implementation of the regulations may result in cost savings to the state by the anticipated reduction in regulatory staff time debating and negotiating risk assessments, screening levels and remediation goals at hazardous substance release sites. However, the potential cost savings is unquantifiable.

DETERMINATION OF NO SIGNIFICANT STATEWIDE ECONOMIC IMPACT

The Department has made a determination through the economic impact assessment that the proposed regulations will not have a significant statewide adverse economic impact directly affecting business, including the ability of California business to compete with businesses in other states.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

EFFECT ON SMALL BUSINESSES

The Department has determined that the proposed regulations will not impact small businesses. First, this action does not change the liability of parties responsible for cleanup. Second, 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. The proposed regulations do not increase cleanup costs or the scale or scope of hazardous substance release cleanups in California. In contrast, implementation of the proposed regulations may result in cost savings to small businesses due to greater certainty in the application of toxicity criteria applied at hazardous substance release sites. Accordingly the Department has determined that the proposed regulations will have no or minimal effect on small businesses.

EFFECT ON HOUSING COSTS

The proposed regulations formally implement procedures currently and historically used for selecting toxicity criteria for human health risk assessments and determining human health-based screening levels and remediation goals for hazardous substance release sites in California. Accordingly, the Department has determined that the proposed regulations will not impact housing costs.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS

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 and implements procedures in place since at least 1994 to assess human health risk at hazardous substance release sites in California. Because the proposed regulations implement procedures that have been in effect, there will be no change to the liability of businesses responsible for cleanup of hazardous substances.

The Department concludes that there will be no direct economic costs to businesses from this action, including the creation or elimination of jobs, the creation of new businesses or elimination of existing businesses, an impact to expansion of businesses currently doing business in the state of California, and the ability of California businesses to compete with businesses in other states. Conversely, there may be fiscal benefits to California business from the greater certainty in the application of toxicity criteria applied at hazardous substance release sites.

BUSINESS REPORTING REQUIREMENT

The proposed regulations apply no reporting requirement to State of California businesses.

CONSIDERATION OF ALTERNATIVES

The Department must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to the affected private persons and equally effective in implementing the statutory policy or other provision of law.

On November 11, 2016, the Department published a “pre-APA” version (Alternative 1) of the draft regulations and on December 12, 2016, held a public workshop to interactively solicit comment and input from the public on the proposed regulations. This pre-APA version was similar to the current proposed regulations (Alternative 3 discussed below), but less descriptive and more rigidly applied the “most protective” toxicity criteria of the three most reliable (scientifically supported) sources listed in the draft rule. It also

incorrectly implied remediation goals must be set at an excess cancer risk of 1×10^{-6} and a non-cancer hazard index (HI) of "1.0" for contaminants at a hazardous waste release site.

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 1×10^{-6} 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 1×10^{-6} 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.

OTHER APPLICABLE REQUIREMENTS PRESCRIBED BY STATUTE

CALIFORNIA ENVIRONMENTAL QUALITY ACT (CEQA) COMPLIANCE

After a preliminary evaluation the Department has determined a Notice of Exemption pursuant to California Code of Regulations, title 14, section 15061(b)(3), is applicable to fulfill CEQA requirements.

CONTACTS

Inquiries regarding technical aspects of the proposed regulations or CEQA documents may be directed to Mr. Kevin Depies at (916) 255-6547 or by email at ToxCriteriaRule@dtsc.ca.gov. If Mr. Depies is not available, contact the Regulations Coordinator, Ms. Jackie Buttle at (916) 255-3730 or regs@dtsc.ca.gov. Note: oral inquiries are not part of the official rulemaking record.

A 45-day public comment period for this rulemaking file, as described above, will commence on August 4, 2017 and close on September 20, 2017 at 11:59 p.m. PDT. During this time, the Department will accept statements, arguments, or contentions and/or supporting documents regarding this rulemaking that must be submitted in writing, or may be presented orally or in writing at the public hearing. Comments must be received by the deadline in order for them to be considered before the Department adopts, amends, or repeals these regulations.

AVAILABILITY OF TEXT OF PROPOSED REGULATIONS, INITIAL STATEMENT OF REASONS, AND RULEMAKING RECORD

Copies of the Notice of Proposed Action, Initial Statement of Reasons, the text of the proposed regulations, all the information upon which its proposal is based, and the express terms of the proposed regulations will be posted to The Department's Internet site at <http://dtsc.ca.gov/LawsRegsPolicies/Regs/Toxicity-Criteria-for-Human-Health-Risk-Assessment.cfm>, or may be obtained from Ms. Jackie Buttle, Regulations Coordinator, as specified below.

After the close of the comment period, the Department may adopt the proposed regulations. If substantial changes are made, the modified full text will be made available for comment for no less than 15 days prior to adoption. Only persons who request these specific proposed regulations, attend the hearing, or provide written or oral comments on the proposed regulations will be sent a copy of the modified text if substantive changes are made.

Once the regulations have been adopted, the Department will prepare a Final Statement of Reasons which updates the Initial Statement of Reasons, summarizes how the Department addressed comments, and includes other materials required by Government Code § 11346.9. Copies of the Final Statement of Reasons may also be obtained from the Regulations Coordinator at the address listed below. A copy of the Final Statement of Reasons, along with the date the rulemaking is filed with the Secretary of State, and the effective date of the regulations will also be posted on the Department's Internet site at: <http://dtsc.ca.gov/LawsRegsPolicies/Regs/Toxicity-Criteria-for-Human-Health-Risk-Assessment.cfm>.

To be included in this regulation package's mailing list and to receive updates of this rulemaking, please visit <http://www.dtsc.ca.gov/ContactDTSC/ELists.cfm> and subscribe to the applicable eList, or to subscribe directly, e-mail: regs@dtsc.ca.gov.

Ms. Jackie Buttle
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If Ms. Buttle is unavailable, please contact Mr. Depies at (916) 255-6547 or by email at ToxCriteriaRule@dtsc.ca.gov.