

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
PROPOSITION 65**

**NOTICE OF PROPOSED RULEMAKING
TITLE 27, CALIFORNIA CODE OF REGULATIONS**

**AMENDMENT TO SECTION 25705
SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK:**

ETHYLENE OXIDE

April 7, 2023

Public Availability Date: April 7, 2023
Deadline for Public Comment: May 23, 2023

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to update a Proposition 65¹ No Significant Risk Level (NSRL) for ethylene oxide by amending Title 27, California Code of Regulations, Section 25705(b)². The proposed updated NSRL for ethylene oxide is 0.058 micrograms per day.

PUBLIC PROCEEDINGS

Written Comment Period

Any written comments concerning this proposed regulatory action, regardless of the form or method of transmission, must be received by OEHHA no later than **May 23, 2023**, the designated close of the written comment period. OEHHA strongly recommends that comments be submitted electronically, rather than in paper form.

Comments may be submitted electronically through our website at <https://oehha.ca.gov/comments>.

Comments submitted in paper form can be mailed, faxed, or delivered in person to the address below, but delays may occur if staff are unable to timely access them.

¹ The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq., referred to herein as "Proposition 65" or "The Act."

² All further regulatory references are to sections of Title 27 of the California Code of Regulations unless otherwise indicated.

Electronic Submission (preferred):

Through OEHHA website at: <https://oehha.ca.gov/comments>

Mailed Submission:

Esther Barajas-Ochoa
Office of Environmental Health Hazard Assessment
P. O. Box 4010
Sacramento, California 95812-4010

In-person delivery submission:

Attention: Esther Barajas-Ochoa
Office of Environmental Health Hazard Assessment
1001 I Street, 23rd Floor
Sacramento, California 95814

OEHHA encourages all commenters to submit their comments in a format compliant with Section 508 of the federal Rehabilitation Act, Web Content Accessibility Guidelines 2.0³ and California Government Code sections 7405 and 11135, so that they can be read using screen reader technology and those with visual impairments are able to listen to them.

OEHHA is subject to the California Public Records Act and other laws that require the release of certain information upon request. If you provide comments, please be aware that your name, address, and e-mail may be available to third parties.

Inquiries concerning the action described in this notice may be directed to Esther Barajas-Ochoa, in writing at the address given above, by email at esther.barajas-ochoa@oehha.ca.gov, or by telephone at: 916-445-6900,

PUBLIC HEARING

A public hearing on these proposed regulatory amendments is not currently scheduled. Pursuant to Government Code section 11346.8, any interested person, or his/her duly authorized representative, may request a public hearing no later than 15 days prior to the close of the written comment period. The hearing would be web-based due to the COVID-19 emergency⁴. To request a hearing, send an e-mail to Esther Barajas-Ochoa at esther.barajas-ochoa@oehha.ca.gov or letter to the address listed above by no later than **May 8, 2023**. If one is scheduled, OEHHA will electronically mail a notice of the

³ <https://www.w3.org/WAI/standards-guidelines/wcag/>

⁴ Senate Bill No. 189 (2022).

hearing to the requester and to interested parties on the Proposition 65 mailing list for regulatory public hearings. The notice will also be posted on the OEHHA web site at least ten days before the public hearing date. The notice will provide the date, time, and instructions for participating in the hearing.

CONTACT

Please direct inquiries concerning the proposed regulatory action described in this notice to Esther Barajas-Ochoa at (916) 445-6900, or by e-mail to esther.barajas-ochoa@oehha.ca.gov. Kristi Morioka is a back-up contact person for inquiries concerning processing of this action and is available at (916) 322-5624 or kristi.morioka@oehha.ca.gov.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Proposition 65 prohibits a person, in the course of doing business, from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual⁵. The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into any source of drinking water⁶.

For carcinogens, an exemption from the warning requirement is provided by the Act when the exposure for which the person is responsible can be demonstrated to produce no significant risk, or when a discharge which otherwise complies with all applicable requirements would not cause any significant amount of the discharged or released chemical to enter any source of drinking water⁷. A determination that a level of exposure poses no significant risk may be made utilizing regulations that have previously been adopted by OEHHA (Sections 25701-25721). Section 25701 describes alternative methods for making such a determination. Section 25705 sets forth the process for determining “no significant risk” levels for purposes of Proposition 65 and establishes those levels for certain listed chemicals.

Details on the basis for the proposed NSRL for ethylene oxide are provided in the Initial Statement of Reasons for this regulatory amendment, which is available on request from Esther Barajas-Ochoa at esther.barajas-ochoa@oehha.ca.gov and is posted on the OEHHA website at www.oehha.ca.gov.

⁵ Health and Safety Code section 25249.6.

⁶ Health and Safety Code section 25249.5.

⁷ Health and Safety Code sections 25249.9 and 25249.10.

This proposed amendment to Section 25705 would change the existing NSRL for ethylene oxide by amending Section 25705(b) as follows (provided in underline and strikeout below):

(b) Chemical name	Level (micrograms per day)
Acrylonitrile	0.7
...	
Ethylene oxide	<u>2 0.058</u>
...	

To develop the proposed updated NSRL for ethylene oxide, OEHHA incorporated significant new data relevant to the estimation of the NSRL that have become available since the existing NSRL for ethylene oxide was adopted in 1988. This includes new data from cancer epidemiology studies and studies of genotoxicity and pharmacokinetics. The proposed level is based on the cancer potency value developed in a 2016 US Environmental Protection Agency (US EPA) risk assessment⁸ based on epidemiologic data from a cohort of more than 18,000 workers with quantitative estimates of exposure to ethylene oxide, assembled by NIOSH^{9,10,11}.

The NSRL for ethylene oxide is based upon the results of the most sensitive scientific study deemed to be of sufficient quality¹².

Anticipated Benefits of the Proposed Regulation

The proposed regulatory amendment provides updated voluntary compliance assistance for businesses subject to the Act. In general, increasing compliance with the Act helps to protect the health and welfare of the California public, in line with the public health goal of Proposition 65. Updating this NSRL using the best available science also provides more accurate and current information about risk levels and a greater public

⁸ US Environmental Protection Agency (US EPA 2016a). Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) in Support of Summary Information on the Integrated Risk Information System (IRIS). Washington, DC, EPA/635/R-16/350Fa. Available from: https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=529970.

⁹ US Environmental Protection Agency (US EPA 2016b). Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide. Appendices. (CASRN 75-21-8). In Support of Summary Information on the Integrated Risk Information System (IRIS). Washington, DC, EPA/635/R-16/350Fb. Available from: https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=529971.

¹⁰ Steenland K, Stayner L, Deddens J (2004). Mortality analyses in a cohort of 18 235 ethylene oxide exposed workers: follow up extended from 1987 to 1998. *Occup Environ Med* 61(1):2-7.

¹¹ Steenland K, Whelan E, Deddens J, Stayner L, Ward E (2003). Ethylene oxide and breast cancer incidence in a cohort study of 7576 women (United States). *Cancer Causes Control* 14(6):531-9.

¹² Section 25703(a)(4).

health benefit to Californians. The updated NSRL does not require, but may encourage, businesses to reduce exposures to the listed chemical to a level that does not cause a significant exposure, thereby providing a public health benefit to Californians. This in turn may reduce resident, worker and environmental exposures to ethylene oxide.

No Inconsistency or Incompatibility with Existing Regulations

After conducting an evaluation on any related regulations in this area, OEHHA has found that these are the only regulations dealing with Proposition 65 No Significant Risk Levels for this specific chemical. Therefore, OEHHA has determined that the proposed regulation is neither inconsistent nor incompatible with existing state regulations. The proposed regulation does not impose any mandatory requirements on businesses, state or local agencies and does not address compliance with any other law or regulation.

RESULTS OF ECONOMIC IMPACT ANALYSIS (Gov. Code section 11346.3(b))

Impact on the Creation, Elimination, or Expansion of Jobs/Businesses in California

In compliance with Government Code section 11346.3, OEHHA has assessed all the elements pursuant to sections 11346.3(b)(1)(A) through (D). In general, it is not possible to quantify any monetary values for this proposed regulatory action given that use of the NSRL is entirely voluntary and the NSRL only provides compliance assistance for businesses subject to the Act.

This regulatory proposal will not affect the creation or elimination of jobs within the State of California. Proposition 65 requires businesses with ten or more employees to provide warnings prior to exposing people to chemicals that are known to cause cancer. The law also prohibits the discharge of listed chemicals into sources of drinking water. Ethylene oxide is listed under Proposition 65; therefore, businesses that manufacture, distribute, sell or use products with ethylene oxide in the state must provide a warning if their product or activity exposes the public or employees to significant amounts of the chemical. The regulatory proposal does not create additional compliance requirements, but instead provides a “safe harbor” value that aids businesses in determining if they are complying with the law.

The proposed NSRL provides compliance assistance to businesses subject to the Act, but does not impose any mandatory requirements on those businesses. Therefore, OEHHA has determined that the proposed regulatory action will not have any impact on the creation or elimination of jobs, the creation of new businesses or the elimination of

existing businesses, or the expansion of businesses currently doing business within the State of California.

By updating the safe harbor levels, this regulatory proposal does not require, but may encourage, businesses to lower the amount of the ethylene oxide emitted into the air from facilities or present in their product to a level that does not cause a significant exposure, thereby providing a public health benefit to California residents and potentially reducing worker exposure.

Use of the NSRL is entirely voluntary for business compliance with the Act, and there is no method to measure whether this regulation will cause a decrease in the amount of the chemical released into the state's environment. By updating the safe harbor levels, the regulatory proposal may encourage businesses to lower the amount of the listed chemical emitted into the air or in their product to a level that does not cause a significant exposure, which may have a beneficial impact on the State's environment.

PEER REVIEW

This notice, the proposed regulatory change, and the Initial Statement of Reasons are being provided to the OEHHA Science Advisory Board's Carcinogen Identification Committee for review and comment¹³.

AUTHORITY

Health and Safety Code Section 25249.12.

REFERENCE

Health and Safety Code Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11.

IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

Because Proposition 65 expressly¹⁴ does not apply to local agencies or school districts, OEHHA has determined the proposed regulatory action would not impose a mandate on local agencies or school districts nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

¹³ Title 27, Cal. Code of Regs., section 25701(e)

¹⁴ See Health and Safety Code section 25249.11 (b)

OTHER NON-DISCRETIONARY COSTS OR SAVINGS

OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

COSTS OR SAVINGS TO STATE AGENCIES

Because Proposition 65 expressly¹⁵ does not apply to any State agency, OEHHA has determined that no savings or increased costs to any State agency will result from the proposed regulatory action.

EFFECT ON FEDERAL FUNDING TO THE STATE

Because Proposition 65 expressly¹⁶ does not apply to any federal agency, OEHHA has determined that no costs or savings in federal funding to the State will result from the proposed regulatory action.

EFFECT ON HOUSING COSTS

OEHHA has determined that the proposed regulatory action will have no effect on housing costs because it provides compliance assistance to businesses subject to Proposition 65 but does not impose any mandatory requirements on those businesses.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

Because the proposed regulatory level provides compliance assistance to businesses subject to Proposition 65, but do not impose any mandatory requirements on those businesses, OEHHA has made an initial determination that the adoption of the regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

The proposed NSRL was developed to provide compliance assistance for businesses in determining whether a warning is required, or a discharge is prohibited. The NSRL provides a level of exposure at or below which a warning is not required, and a

¹⁵ See Health and Safety Code section 25249.11 (b)

¹⁶ See Health and Safety Code section 25249.11 (b)

discharge is not prohibited. Use of the NSRL is not mandatory. The implementing regulations allow a business to calculate its own level and provide guidance in order to assist businesses in doing so¹⁷. However, conducting such a process can be expensive and time consuming, and the resulting levels may not be defensible in an enforcement action. OEHHA 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

OEHHA has determined that the proposed regulation will not impose any mandatory requirements on small business. Rather, the proposed NSRL will provide compliance assistance for small businesses subject to Proposition 65 because they will help businesses determine whether or not an exposure for which they are responsible is subject to the warning requirement or discharge prohibition of Proposition 65.

CONSIDERATION OF ALTERNATIVES

Government Code section 11346(a)(13) requires that a rulemaking agency must determine that no reasonable alternative considered by the agency or that has otherwise been identified and brought to the attention of the agency 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 affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposal described in this Notice. OEHHA has determined that there is no alternative to the proposed regulation that is less burdensome and equally effective in achieving the purposes of the regulation in a manner that achieves the purposes of the statute.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS

OEHHA has prepared and has available for public review an Initial Statement of Reasons for the regulation, all the information upon which the regulation is based, and the text of the regulation. A copy of the Initial Statement of Reasons, the text of the regulation and the documents relied on to develop the proposed regulation are available upon request from OEHHA at the address and telephone number indicated above. These documents are also posted on OEHHA's website at www.oehha.ca.gov.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

¹⁷ Title 27, Cal. Code of Regs., section 25701 et seq.

The full text of any regulation which is changed or modified from the express terms of this proposed action will be made available at least 15 days prior to the date on which OEHHA adopts the resulting regulation. Notice of the comment period on changed regulations and the full text will be mailed to individuals who testified or submitted written comments at the public hearing, if held, or whose comments were received by OEHHA during the public comment period, and anyone who requests notification from OEHHA of the availability of such changes. Copies of the notice and the changed regulation will also be available on the OEHHA website at www.oehha.ca.gov.

FINAL STATEMENT OF REASONS

A copy of the Final Statement of Reasons for this regulatory action may be obtained, when it becomes available, from OEHHA at the address and telephone number indicated above, and on the OEHHA website at www.oehha.ca.gov.

OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT

David Edwards, Ph.D.
Chief Deputy Director

Dated: April 7, 2023