INITIAL STATEMENT OF REASONS
TITLE 27, CALIFORNIA CODE OF REGULATIONS

PROPOSED AMENDMENT TO

SECTION 25705(b), SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK: TRICHLOROETHYLENE

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 PROPOSITION 65

PURPOSE AND BACKGROUND OF PROPOSED AMENDMENTS OF REGULATION

This proposed regulatory amendment would adopt updated no significant risk levels (NSRLs) for trichloroethylene exposure under Proposition 65[1] in Title 27, California Code of Regulations, section 25705(b).[2] The proposed levels are 14 micrograms (µg) per day for oral exposure and 50 µg per day for inhalation exposure. These levels incorporate significant new data relevant to the estimation of NSRLs that have become available since the existing NSRLs for trichloroethylene were adopted in 1992, including data from mechanistic studies, studies of pharmacokinetics, and numerous cancer epidemiology studies. The proposed levels are based on cancer potency values developed in a 2011 U.S. Environmental Protection Agency (U.S. EPA) risk assessment.[3] The Office of Environmental Health Hazard Assessment (OEHHA) reviewed the 2011 U.S. EPA trichloroethylene risk assessment and determined that the derivations of the cancer potency values were consistent with the guidelines set forth in Section 25703.

Proposition 65 was enacted as a voters' initiative on November 4, 1986. OEHHA is the lead state entity responsible for the implementation of Proposition 65.[4] OEHHA has the authority to adopt and amend regulations to further the purposes

[1] The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq., commonly known as Proposition 65, hereafter referred to as "Proposition 65" or "The Act".
[2] All further regulatory references are to sections of Title 27 of the Cal. Code of Regs., unless otherwise indicated.
[3] U.S. EPA, 2011. Toxicological Review of Trichloroethylene (CAS No. 79-01-6). In Support of Summary Information on the Integrated Risk Information System (IRIS). September 2011, U.S. EPA, Washington DC [Available at URL: http://www.epa.gov/iris/supdocs/0199index.html].
[4] Title 27, California Code of Regulations, section 25102(o).

of the Act.[5] The Act requires businesses to provide a warning when they cause an exposure to a chemical listed as known to cause cancer or reproductive toxicity. The Act also prohibits the discharge of listed chemicals to sources of drinking water.

Trichloroethylene was listed as known to the State to cause cancer under Proposition 65 on April 1, 1988. In 1992, NSRLs for trichloroethylene were derived based on the Proposition 65 regulatory guidance and the best available science at the time and adopted in Section 25705(b). Since these levels were adopted, significant new scientific information from pharmacokinetic, mechanistic and epidemiological studies relevant to the estimation of NSRLs for trichloroethylene has become available. The U.S. EPA's 2011 extensive review and analysis incorporates the latest available toxicological information on the carcinogenicity of trichloroethylene and derives cancer potencies for the chemical, namely an oral slope factor and an inhalation unit risk. OEHHA's review of the U.S. EPA assessment found it to be a reliable scientific basis for updating the NSRLs that is consistent with Section 25703 guidance. The trichloroethylene risk assessment underwent internal and external scientific review, as well as a public comment process, before being released as a final document by U.S. EPA.

In the 2011 trichloroethylene risk assessment, the U.S. EPA described its findings as follows:

> "…TCE *[trichloroethylene]* is characterized as 'carcinogenic to humans' by all routes of exposure. This conclusion is based on convincing evidence of a causal association between TCE exposure in humans and kidney cancer. The human evidence of carcinogenicity from epidemiologic studies of TCE exposure is strong for non-Hodgkin Lymphoma *[NHL]* but less convincing than for kidney cancer, and more limited for liver and biliary tract cancer. Less human evidence is found for an association between TCE exposure and other types of cancer, including bladder, esophageal, prostate, cervical, breast, and childhood leukemia. Further support for the characterization of TCE as 'carcinogenic to humans' by all routes of exposure is derived from positive results in multiple rodent cancer bioassays in rats and mice of both sexes, similar toxicokinetics between rodents and humans, mechanistic data supporting a mutagenic mode of action for kidney tumors, and the

[5] Health and Safety Code, section 25249.12(a).

> lace of mechanistic data supporting the conclusion that any of the mode(s) of action for TCE-induced rodent tumors are irrelevant to humans." (U.S. EPA, 2011, page 6-42)
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> "For cancer, the inhalation unit risk is **2×10^{-2} per ppm [4×10^{-6} per µg/m^3]**, based on human kidney cancer risks reported by Charbotel *et al.* (2006)[6] and adjusted, using human epidemiological data, for potential risk for NHL and liver cancer. The oral slope factor for cancer is **5×10^{-2} per mg/kg/day**, resulting from PBPK *[physiologically-based pharmacokinetic]* model-based route-to-route extrapolation of the inhalation unit risk estimate based on the human kidney cancer risks reported in Charbotel *et al.* (2006) and adjusted, using human epidemiological data, for potential risk for NHL and liver cancer. There is high confidence in these unit risks for cancer, as they are based on good-quality human data, as well as being similar to unit risk estimates based on multiple rodent bioassays. There is both sufficient weight of evidence to conclude that TCE operates through a mutagenic mode of action for kidney tumors and a lack of TCE-specific quantitative data on early-life susceptibility." (U.S. EPA, 2011, page 6-43, emphasis added)

OEHHA used the inhalation unit risk and oral slope values as the bases for calculating the proposed oral and inhalation NSRLs for trichloroethylene, which will replace and update the levels adopted in 1992. In addition to changing the numeric values of the NSRLs, OEHHA is proposing to change the term used to designate the route of exposure from "ingestion" to "oral." OEHHA considers these terms to be interchangeable in the context of Proposition 65 exposures, and is making this change to be consistent with its current practice.

The NSRL can be expressed as the daily intake level posing no significant risk of cancer, in units of µg (micrograms) per day. In general, daily intake levels associated with lifetime cancer risks above one per one-hundred thousand (which can be expressed in scientific terms as 10^{-5}) exceed the NSRL for cancer under Proposition 65 (Section 25703(b)).

The oral NSRL can be calculated from the U.S. EPA oral slope factor as follows. The risk level of 10^{-5} is divided by the oral slope factor, a measure of the

[6] Charbotel B, Fevotte J, Hours M, Martin J-L, Bergeret A. 2009. Case-control study on renal cell cancer and occupational exposure to trichloroethylene. Part II: Epidemiological aspects. Ann Occup Hyg 50:777-787. http://dx.doi.org/10.1093/annhyg/mel039.

carcinogenic activity of the chemical. Because the oral slope factor is expressed in units of one divided by milligram (mg) per kilogram (kg) bodyweight per day ($(mg/kg\text{-}day)^{-1}$), the result of the calculation is a dose associated with a 10^{-5} risk in units of mg/kg-day. This dose then can be converted to an intake amount in units of mg per day by multiplying by the bodyweight for humans. When the calculation is for the general population the bodyweight is assumed to be 70 kg in NSRL calculations (Section 25703(a)(8)). The intake can be converted to a µg–per-day amount by multiplying by 1000. This sequence of calculations can be expressed mathematically as:

$$\text{oral NSRL} = \frac{10^{-5} \times 70\ \text{kg}}{\text{oral slope factor}} \times 1000\ \mu\text{g/mg}.$$

The oral slope factor for trichloroethylene derived in the U.S. EPA risk assessment is 0.05 per mg/kg-day. Inserting this number into the equation above results in an oral NSRL of 14 µg/day.

The inhalation unit risk value for trichloroethylene derived in the U.S. EPA risk assessment is 2×10^{-2} ppm (parts per million), or 4×10^{-6} per $\mu g/m^3$ (micrograms per cubic meter). The inhalation NSRL can be derived from this unit risk expressed in units $\mu g/m^3$ by the following equation:

$$\text{inhalation NSRL} = \frac{10^{-5} \times 20\ \text{m}^3/\text{day}}{\text{inhalation unit risk}}.$$

20 m^3/day is the assumed breathing rate for the general human population. Inserting inhalation unit risk of 4×10^{-6} per $\mu g/m^3$ into the equation above results in an inhalation NSRL of 50 µg/day.

PROPOSED REGULATORY AMENDMENT

The proposed change to Section 25705(b) is provided below, in underline and strikeout.

(b) Levels of exposure deemed to pose no significant risk may be determined by the lead agency based on a risk assessment conducted by the lead agency pursuant to the guidelines set forth in Section 25703, or a risk assessment reviewed by the lead agency and determined to be consistent with the guidelines set forth in Section 25703.

(1) The following levels based on risk assessments conducted or reviewed by the lead agency shall be deemed to pose no significant risk:

Chemical name	Level (micrograms per day)
Acrylonitrile	0.7
…	
Toxaphene	0.6
Trichloroethylene	~~50~~14 (~~ingestion~~oral)
	~~80~~50 (inhalation)
2,4,6-Trichlorophenol	10
…	

PROBLEM BEING ADDRESSED BY THIS PROPOSED RULEMAKING

Proposition 65 does not provide guidance regarding how to determine whether a warning is required or a discharge is prohibited. OEHHA is the implementing agency for Proposition 65 and has the resources and expertise to examine the scientific literature and calculate levels of exposure, in this case oral and inhalation NSRLs, that do not require a warning or for which a discharge is not prohibited.

NECESSITY

This proposed regulatory amendment would adopt NSRLs that conform with the Proposition 65 implementing regulations and reflects the currently available scientific knowledge about trichloroethylene. The NSRLs provide assurance to the regulated community that exposures or discharges at or below them are considered not to pose a significant risk of cancer. Exposures at or below the NSRLs are exempt from the warning and discharge requirements of Proposition 65.[7]

BENEFITS OF THE PROPOSED REGULATION: See ”Benefits of the Proposed Regulation” under ECONOMIC IMPACT ANALYSIS below.

[7] Health and Safety Code sections 25249.9(b) and 25249.10(c)

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS, OR DOCUMENTS

OEHHA reviewed the 2011 U.S. EPA trichloroethylene risk assessment[8], determined that the risk assessment's derivations of the oral and inhalation unit risk values were consistent with the guidelines set forth in Section 25703, and used these values as the bases for calculating the oral and inhalation NSRLs for trichloroethylene proposed for adoption into Section 25705(b). The 2011 U.S. EPA risk assessment provides the bases for calculating the NSRLs for the chemical. A copy of the 2011 U.S. EPA trichloroethylene risk assessment will be included in the regulatory file for this action, and is available from OEHHA upon request.

REASONABLE ALTERNATIVES TO THE REGULATION AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES

The NSRLs provide "safe harbor" values that aid businesses in determining if they are complying with the law. The alternative to the amendment to Section 25705(b) would be to not promulgate updated NSRLs for the chemical. Failure to promulgate an updated NSRL would leave the business community without the scientifically most appropriate "safe harbor" level to assist them in determining compliance with Proposition 65.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESSES

OEHHA is not aware of significant cost impacts that small businesses would incur in reasonable compliance with the proposed action. In addition, Proposition 65 is limited by its terms to businesses with 10 or more employees (Health and Safety Code, section 25249.11(b)) so it has no effect on very small businesses.

[8] U.S. EPA, 2011. Toxicological Review of Trichloroethylene (CAS No. 79-01-6). In Support of Summary Information on the Integrated Risk Information System (IRIS). September 2011, U.S. EPA, Washington DC [Available at URL: http://www.epa.gov/iris/supdocs/0199index.html].

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS

Because the proposed updated NSRLs provide “safe harbor” levels for businesses to use when determining compliance with Proposition 65, OEHHA does not anticipate that the regulation will have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS CONTAINED IN THE CODE OF FEDERAL REGULATIONS

Proposition 65 is a California law that has no federal counterpart. There are no federal regulations addressing the same issues and, thus, there is no duplication or conflict with federal regulations.

ECONOMIC IMPACT ANALYSIS
Gov. Code section 11346.3(b)

It is not possible to quantify any monetary values for this proposed regulation given that its use is entirely voluntary and it only provides compliance assistance for businesses subject to the Act.

Impact on the Creation, Elimination, or Expansion of Jobs/Businesses in California: 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 when they expose people to chemicals that are known to cause cancer or developmental or reproductive harm. The law also prohibits the discharge of listed chemicals into sources of drinking water. Trichloroethylene is listed under Proposition 65; therefore businesses and individuals who manufacture, distribute or sell products with trichloroethylene in the state must provide a warning if their product or activity exposes the public or employees to this chemical.

Benefits of the Proposed Regulation: The NSRLs provide "safe harbor" values that aid businesses in determining if they are complying with the law. Some businesses may not be able to afford the expense of establishing or updating an NSRL and therefore may be exposed to litigation for a failure to warn or for a prohibited discharge of the listed chemical. Adopting this regulation will save these businesses those expenses and may reduce litigation costs. By updating the safe harbor levels, this regulatory proposal does not require, but may encourage, businesses to lower the amount of the listed chemical in their product to a level that does not cause a significant exposure, thereby providing a public health benefit to Californians.

Problem being addressed by this proposed rulemaking: Proposition 65 does not provide specific guidance regarding how to determine whether a warning is required or a discharge is prohibited. OEHHA is the implementing agency for Proposition 65 and has the resources and expertise to examine the scientific literature and calculate a level of exposure that does not require a warning or trigger the discharge prohibition.

How the proposed regulation addresses the problem: The proposed regulation would adopt updated specific regulatory levels for a listed chemical to provide compliance assistance for businesses that are subject to the requirements of the Act. While OEHHA is not required to adopt such levels,

adopting them provides a “safe harbor” for businesses and provides certainty that they are complying with the law if the exposures or discharges they cause are below the established level.

Reasonable alternatives to the proposed regulation: OEHHA determined that the only alternative to the proposed regulation would be to not adopt updated NSRLs for this chemical. This alternative was rejected because it would fail to provide businesses with the certainty that the updated NSRLs can provide.

Results: By providing updated NSRLs, this regulatory proposal spares businesses the expense of calculating their own updated NSRLs and may also enable them to reduce or avoid litigation costs. In addition, the updated NSRLs do not require, but may encourage, businesses to lower the amount of the listed chemical in their product to a level that does not cause a significant exposure, thereby providing a public health benefit to Californians.