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 25805
SPECIFIC REGULATORY LEVELS:
CHEMICALS CAUSING REPRODUCTIVE TOXICITY

METHANOL

MARCH 16, 2012

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to establish Proposition 65[1] Maximum Allowable Dose Levels for methanol of 47,000 micrograms per day for inhalation and 23,000 micrograms per day for ingestion by amending Section 25805(b).

PUBLIC PROCEEDINGS

Any written comments concerning this proposed action, regardless of the form or method of transmission, must be received by OEHHA by 5:00 p.m. on **April 30, 2012**, the designated close of the written comment period. All comments received will be posted on the OEHHA website at the close of the public comment period.

The public is encouraged to submit written information via e-mail, rather than in paper form. Send e-mail comments to P65Public.Comments@oehha.ca.gov. Please include "METHANOL MADL" in the subject line. Hard-copy comments may be mailed, faxed, or delivered in person to the appropriate address below.

[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."

Mailing Address: Ms. Susan Luong
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Sacramento, California 95812-4010
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Sacramento, California 95814

A public hearing on this proposed regulatory amendment will be scheduled on request. To request a hearing send an e-mail to Susan Luong at susan.luong@oehha.ca.gov or to the address listed above by no later than **April 16, 2012**, which is 15 days before the close of the comment period. OEHHA will mail a notice of the hearing to the requester and 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 location of the hearing.

If a hearing is scheduled and you have special accommodation or language needs, please contact Susan Luong at (916) 327-3015 or susan.luong@oehha.ca.gov at least one week in advance of the hearing. TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

CONTACT

Please direct inquiries concerning the proposed regulatory action described in this notice to Susan Luong, in writing at the address given above, via e-mail to susan.luong@oehha.ca.gov or by telephone at (916) 327-3015. Monet Vela is a back-up contact person for inquiries concerning processing of this action and is available at monet.vela@oehha.ca.gov or (916) 323-2517.

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 individual (Health and Safety Code section 25249.6). 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 water (Health and Safety Code section 25249.5). Warnings are not required and the

discharge prohibition does not apply when exposures are insignificant.[2] The MADL safe harbors provide guidance for determining when this is the case.[3]

Details on the bases for the proposed MADLs for methanol are provided in the initial statement of reasons for this regulatory amendment, which is available on request from Susan Luong and is posted on the OEHHA web site at www.oehha.ca.gov.
This proposed regulation sets forth MADLs for adoption into Section 25805 that were derived using scientific methods outlined in Section 25803.

The proposed regulation would adopt the following MADLs for methanol, by amending Section 25805 as follows (addition in underline):

(b) Chemical Name	Level (Micrograms/day)
Methanol	47,000 (inhalation)
	23,000 (oral)

OEHHA relied on a review of studies identified in the 2003 National Toxicology Program (NTP) final report to develop the proposed MADLs. A search for any relevant studies published after the report was completed was also conducted. No additional relevant studies were identified. NTP identified the most sensitive study of the developmental toxicity of methanol, the study by Rogers et al. (1993). This included an oral experiment and an inhalation experiment using methanol. OEHHA concurs with NTP's selection.

This notice and the initial statement of reasons are being provided to the OEHHA Science Advisory Board's Developmental and Reproductive Toxicant (DART) Identification Committee for review and comment.

Specific Benefits Anticipated by the Regulation: See "Benefits of the Proposed Regulation" under "RESULTS OF THE ECONOMIC IMPACT ANALYSIS" below.

OEHHA has determined that the proposed regulation is neither inconsistent nor incompatible with existing state regulations because it provides compliance assistance to businesses subject to the Act, but does not impose any mandatory requirements on those businesses, state or local agencies and does not address compliance with any other law or regulation.

[2] Health and Safety Code sections 25249.9 and 25249.10
[3] See Sections 25801 to 25805

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

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. Methanol is listed under Proposition 65, therefore businesses and individuals who manufacture, distribute or sell products with methanol in the state must provide a warning if their product or activity exposes the public or employees to this chemical.

Because the proposed regulatory levels provide compliance assistance to businesses subject to the Act, but do not impose any mandatory requirements on those businesses, 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.

Benefits of the Proposed Regulation: Some businesses may not be able to afford the expenses of establishing an NSRL or MADL 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 providing a safe harbor level, this regulatory proposal does not require, but may encourage businesses to lower the amount of the listed chemical in their products to a level that does not cause a significant exposure. This in turn may reduce state's residents, worker and environmental exposures to chemicals that cause cancer, developmental or reproductive harm.

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 expressly[4] 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. 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 expressly[5] 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 expressly[6] 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 the Act, 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 levels provide compliance assistance to businesses subject to the Act, 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.

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[4] See Health and Safety Code section 25249.11(b)
[5] See Health and Safety Code section 25249.11(b)

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

The proposed MADLs were developed to provide compliance assistance for these businesses in determining whether a warning is required or a discharge is prohibited. The MADLs provide levels of exposure below which a warning is not required and a discharge is not prohibited. Use of the MADLs is not mandatory. The implementing regulations allow a business to calculate its own level and provide guidance in order to assist businesses in doing so.[7] However, conducting such a process can be expensive and time consuming, and the resulting levels may not be defensible in an enforcement action.

EFFECT ON SMALL BUSINESSES

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

CONSIDERATION OF ALTERNATIVES

Government Code Section 11346.5(a)(13) requires that OEHHA must determine that no reasonable alternative considered by OEHHA or that has otherwise been identified and brought to the attention of OEHHA would be more effective in carrying out the purpose for which the action is proposed, or 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.

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 documents used by OEHHA 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 Web site at www.oehha.ca.gov.

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[6] See Health and Safety Code section 25249.11(b)
[7] Title 27, Cal. Code of Regs., section 25801 et seq.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

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 Web site 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

Allan Hirsch
Chief Deputy Director

Dated: March 16, 2012

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
PROPOSITION 65

INITIAL STATEMENT OF REASONS
TITLE 27, CALIFORNIA CODE OF REGULATIONS

PROPOSED AMENDMENT TO
SECTION 25805(b), SPECIFIC REGULATORY LEVELS: CHEMICALS CAUSING REPRODUCTIVE TOXICITY

METHANOL

PURPOSE AND BACKGROUND OF PROPOSED AMENDMENT

PURPOSE

This proposed regulatory amendment is to adopt maximum allowable dose levels (MADLs) for methanol under Proposition 65[1] in Title 27, California Code of Regulations, section 25805(b) [2]. The proposed inhalation MADL for methanol of 47,000 micrograms per day and the proposed oral MADL for methanol of 23,000 micrograms per day were derived using scientific methods outlined in Section 25803.

PROPOSITION 65 AND LISTING OF METHANOL

Proposition 65 was enacted as a voters' initiative on November 4, 1986. The Office of Environmental Health Hazard Assessment (OEHHA) within the California Environmental Protection Agency is the lead state entity responsible for the implementation of Proposition 65.[3] OEHHA has the authority to promulgate and amend regulations to further the purposes of the Act[4]. The Act requires businesses to provide a warning when they cause an exposure to a chemical listed as known to the state to cause cancer or reproductive toxicity. The Act also prohibits the discharge of listed chemicals to sources of drinking water.

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[1] The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et. seq., hereafter referred to as "Proposition 65" or "The Act".
[2] All subsequent citations are to Title 27, California Code of Regulations, unless otherwise noted.
[3] Cal. Code of Regs., Title 27, Division 4. Chapter 1. Article 1. Preamble(a).
[4] Health and Safety Code, section 25249.12(a).

On March 16, 2012, methanol was added to the Proposition 65 list as known to the state to cause reproductive toxicity, based on formal identification as causing reproductive toxicity (developmental endpoint) by the National Toxicology Program (NTP) in a report by its Center for the Evaluation of Risks to Human Reproduction (CERHR) (NTP, 2003). The NTP (solely as to final reports of the CERHR) is identified as an authoritative body for reproductive toxicity under Proposition 65 (Section 25306(l)).

STUDY SELECTION

OEHHA relied on the attached Economic Impact Assessment in developing this proposed regulation.

As for the scientific basis for the proposed regulation, OEHHA reviewed the studies identified in the NTP (2003) final report, and conducted a search for any relevant studies published after the report was completed. No additional relevant studies were identified. NTP identified the most sensitive study of the developmental toxicity of methanol, the study by Rogers et al. (1993)[5]. OEHHA concurs with that selection.

In the study by Rogers et al. (1993)[6], pregnant Crl:CD-1 mice were exposed to methanol vapor at concentrations of 0, 1,000, 2,000, 5,000 7,500, 10,000 or 15,000 parts per million (ppm) for seven hours per day on days 6-15 of gestation. There was a dose-related and statistically significant decrease in the number of live pups per litter in groups exposed to methanol vapor doses of 7,500 ppm and higher; there was also a dose-related increase in females with fully resorbed litters at 10,000 ppm and higher. Fetal body weights were significantly reduced at 10,000 ppm and higher. The incidence of cleft palate was increased at doses of 5,000 ppm and greater. The percent incidence/litter of exencephaly was significantly increased at the 5,000, 10,000 and 15,000 ppm doses (not statistically significant at 7,500 ppm). The most sensitive effect was increased incidence of cervical ribs at 2,000 ppm. Thus, 1,000 ppm was identified as a no observable effect level (NOEL). For purposes of Proposition 65, this study by Rogers et al. is the most sensitive study deemed to be of sufficient quality (Section 25803(a)(4)).

[5] Rogers JM, Mole ML, Chernoff N, et al. (1993). The developmental toxicity of inhaled methanol in the CD-1 mouse, with quantitative dose-response modeling for estimation of benchmark doses. *Teratology* **47**:175-188.
[6] Rogers JM, Mole ML, Chernoff N, et al. (1993).

In this same study by Rogers et al. (1993), additional pregnant mice were exposed to methanol by the oral route to determine comparability of effects between exposure routes. On gestation days (gd) 6 –15, 20 mice were gavaged with methanol twice daily at a dose of 2,000 milligrams per kilogram of body weight (mg/kg) for a total dose of 4,000 mg/kg/day and 8 control pregnant mice were gavaged twice daily with water. The dose was selected to produce blood methanol levels observed in the inhalation study at the higher doses. Twice daily gavage doses of 2,000 mg/kg methanol (8 mice) on gd 6 –15 gave a pattern of response similar to that seen in the mouse group exposed to 10,000 ppm by inhalation. Fetal effects in the treated group included decreased fetal weight, increased resorptions, decreased live fetuses, and an increased incidence of fetuses/litter with cleft palate or exencephaly. Thus, 4,000 mg/kg/day is a lowest observable effect level (LOEL) for oral exposure to methanol.

MADL CALCULATION

Inhalation:
The following calculations were performed in accordance with Section 25803 to derive the inhalation MADL for methanol:

- Conversion of air concentration from ppm to milligrams per cubic meter (mg/m^3) using a conversion factor of 1.33 mg/m^3 per ppm [7]:
  $$(1{,}000 \text{ ppm} \times 1.33 \text{ [mg/m}^3\text{/ppm]}) = 1{,}330 \text{ mg/m}^3$$

- Conversion of air concentration for 7 hour (h) exposure to a 24 h day:
  $$1{,}330 \text{ mg/m}^3 \times (7 \text{ h} \div 24 \text{ h}) = 387.9 \text{ mg/m}^3$$

- Calculation of NOEL dose for 30 gram (g) mouse with an inhalation rate of 0.063 m^3/day[8,9]:
  $$(387.9 \text{ mg/m}^3 \times 0.063 \text{ m}^3\text{/day}) \div (0.030 \text{ kg}) = 814.6 \text{ mg/kg/day}$$

- Calculation of NOEL dose for a 58 kg woman:
  $$814.6 \text{ mg/kg/ day} \times 58 \text{ kg} = 47{,}248 \text{ mg/day},$$
  or 47,000 mg/day after rounding

[7] NIOSH Pocket Guide to Chemical Hazards, U.S. Dept. of Health and Human Services,
[8] Bond JA, Dahl AR, Henderson RF, Dutcher JS, Mauderly JL, Birnbaum LS (1986). Species differences in the disposition of inhaled butadiene. *Toxicol Appl Pharmacol* **84**: 617-627.
[9] Depledge MH (1985). Respiration and lung function in the mouse, *Mus musculus* (with a note on mass exponents and respiratory variables). *Respir Physiol* **60**: 83-94.

- The MADL is derived by dividing the NOEL by one thousand (Section 25801(b)(1)). Thus, the adjusted NOEL was divided by 1,000 to obtain the MADL:

  $\mathbf{MADL_{inhalation}}$ = 47,000 mg/day ÷ 1000 = **47,000 micrograms/day**

This MADL applies to exposure to methanol by the inhalation route.

Oral:

The following calculations were performed in accordance with Section 25803 to derive the oral MADL for methanol:

- By regulation[10], where data do not allow the determination of a NOEL, the LOEL shall be divided by 10 to establish a NOEL for purposes of assessment:

  4,000 mg/kg/ day ÷ 10 = 400 mg/kg/ day

- Calculation of NOEL dose for a 58 kg woman:

  400 mg/kg/ day × 58 kg = 23,200 mg/day,
  or 23,000 mg/day after rounding

- The MADL is derived by dividing the NOEL by one thousand (Section 25801(b)(1)). Thus, the adjusted NOEL was divided by 1,000 to obtain the MADL:

  $\mathbf{MADL_{oral}}$ = 23,000 mg/day ÷ 1000 = **23,000 micrograms/day**

This MADL applies to exposure to methanol by the oral route.

PROPOSED REGULATORY AMENDMENT

The proposed change to Section 25805(b) is provided below in underline:

Chemical name	*Level (micrograms per day)*
…	
Methanol	47,000 (inhalation) 23,000 (oral)

…

[10] Title 27, Cal. Code of Regs., section 25803(a)(8).

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 a level of exposure, in this case a MADL, that does not require a warning or a discharge is not prohibited.

NECESSITY

This proposed regulatory amendment would adopt MADLs that conform with the Proposition 65 implementing regulations and reflects the currently available scientific knowledge about methanol. The MADLs provide assurance to the regulated community that exposures or discharges at or below them are considered not to pose a significant risk of developmental or reproductive harm. Exposures at or below the MADLs are exempt from the warning and discharge requirements of Proposition 65.[11]

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

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

OEHHA reviewed the 2003 National Toxicology Program (NTP) Monograph on the Potential Human Reproductive and Developmental Effects of Methanol from the NTP Center for the Evaluation of Risks to Human Reproduction (CERHR).[12] OEHHA determined that the most sensitive study of developmental toxicity identified by NTP-CERHR (Rogers et al., 1993)[13] was of sufficient quality as required by Section 25803(a)(5), and that there were no subsequently published studies that were more sensitive. OEHHA used the values from this study as the bases for calculating the oral and inhalation MADLs for methanol proposed for adoption into Section 25805(b). A copy of the 2003 NTP-CERHR methanol monograph and the study by Rogers et al. (1993) will be included in the regulatory file for this action, and are available from OEHHA upon request.

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

[12] National Toxicology Program – Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR, 2003). *NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Methanol*. NIH Publication No. 04-4478.

[13] Rogers JM, Mole ML, Chernoff N, et al. (1993). The developmental toxicity of inhaled methanol in the CD-1 mouse, with quantitative dose-response modeling for estimation of benchmark doses. *Teratology* **47**:175-188.

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

The MADL provides a "safe harbor" value that aids businesses in determining if they are complying with the law. The alternative to the amendment to Section 25805(b) would be to not promulgate a MADL for the chemical. Failure to promulgate a MADL would leave the business community without a "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.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS

Because the proposed MADL provides a "safe harbor" level 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. Methanol is listed under Proposition 65; therefore, businesses and individuals who manufacture, distribute or sell products with methanol 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 MADL provides a “safe harbor” value that aids businesses in determining if they are complying with the law. Some businesses may not be able to afford the expense of establishing a MADL 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 providing a safe harbor level, 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 a specific regulatory level 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 MADLs for this chemical. This alternative was rejected because it would fail to provide businesses with the certainty that the MADLs can provide.

Results: By providing a MADL, this regulatory proposal spares businesses the expense of calculating their own MADL and may also enable them to reduce or avoid litigation costs. In addition, the MADL 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.

TITLE 27, CALIFORNIA CODE OF REGULATIONS

CHAPTER 1. SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

ARTICLE 8. NO OBSERVABLE EFFECT LEVELS

Section 25805. Specific Regulatory Levels: Chemicals Causing Reproductive Toxicity

Amend Section 25805 (b) as follows:

(b) Chemical Name	*Level (micrograms/day)*
Acrylamide	140

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Linuron	460
Methanol	47,000 (inhalation) 23,000 (oral)
Methyl bromide as a structural fumigant	810 (inhalation)

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NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.