

**INITIAL STATEMENT OF REASONS
TITLE 27, CALIFORNIA CODE OF REGULATIONS**

**PROPOSED AMENDMENT TO:
SECTION 25705(c) SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT
RISK
SECTION 25805(b) SPECIFIC REGULATORY LEVELS: CHEMICALS CAUSING
REPRODUCTIVE TOXICITY**

POLYCHLORINATED BIPHENYLS (FOOD CHAIN EXPOSURES)

APRIL 13, 2012

PURPOSE AND BACKGROUND OF PROPOSED AMENDMENTS OF REGULATION

These proposed regulatory amendments would update a No Significant Risk Level (NSRL) and adopt a Maximum Allowable Dose Level (MADL) for polychlorinated biphenyls (food chain exposures) under Proposition 65¹ in Title 27, California Code of Regulations². The proposed NSRL of 0.35 micrograms per day ($\mu\text{g}/\text{day}$) for Section 25705(c) is based on the cancer potency value developed in a U.S. Environmental Protection Agency (U.S. EPA) risk assessment.³ The proposed MADL of 2.3 $\mu\text{g}/\text{day}$ for Section 25805(b) is based on a primate study and was derived using the methods described in Section 25803. The proposed NSRL and MADL only apply to environmental mixtures of PCBs that are in the food chain, such as are found in meats, fish, shellfish, eggs, dairy products, and other food products. They do not apply to mixtures of water-soluble polychlorinated biphenyls (PCBs) in aqueous solution.

Proposition 65 was enacted as a voters' initiative on November 4, 1986. The Office of Environmental Health Hazard Assessment (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 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

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, 1996. PCBs: Cancer Dose Response Assessment and Application to Environmental Mixtures, EPA/600/P-96/001F, National Center for Environmental Assessment, Office of Research and Development, U.S. Environmental Protection Agency, Washington, DC.

⁴ Title 27, Cal. Code of Regs. section 25102(o).

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

cancer or reproductive toxicity. The Act also prohibits the discharge of listed chemicals to sources of drinking water. Warnings are not required and the discharge prohibition does not apply when exposures are insignificant. The MADL and NSRL safe harbors provide guidance for determining when this is the case.

PCBs (containing 60% or more chlorine by molecular weight) were listed as known to the State to cause cancer under Proposition 65 on January 1, 1988 based on a finding by the state's qualified experts. PCBs as an entire class were listed under the Labor Code mechanism on October 1, 1989. PCBs were listed as known to the State to cause reproductive toxicity on January 1, 1991, based on a finding by the state's qualified experts that PCBs cause developmental toxicity, a type of reproductive toxicity.

Proposed Section 25705(c): NSRL for PCBs (food chain exposures)

In 1989, an NSRL for PCBs of 0.09 micrograms (μg) per day was derived and adopted⁶ in Section 25705(c).⁷ It was based on a cancer potency value of 7.7 milligrams, per kilogram bodyweight per day (mg/kg-day) published in a list of cancer potency values in the U.S. EPA 1987 report "Health Assessment Document for Beryllium." This U.S. EPA cancer potency value has been superseded by values published by the U.S. EPA in 1996 in its document "PCBs: Cancer Dose Response Assessment and Application to Environmental Mixtures."⁸

U.S. EPA provides values for different types of PCB mixtures. The NSRL provided here applies to PCBs associated with the food chain, to which people are exposed through food consumption. This includes PCBs in fish, fish oil, eggs, meat, shellfish, poultry, and dairy products. The NSRL is derived from the upper bound on the cancer slope factor of 2.0 per mg/kg-day provided for in the 1996 U.S. EPA risk assessment for PCBs of high persistence. This is the same value used by OEHHA to develop fish advisories for PCBs in California sport fish.⁹

⁶ Final Statement of Reasons, Title 22, California Code of Regulations, Section 12701 *et seq.* – No Significant Risk Levels; Sections 12801 *et seq.* – No Observed Effect Levels, Health and Welfare Agency, June 1989, available at: http://www.oehha.ca.gov/prop65/law/pdf_zip/Art7_8FSRJune1989.pdf PCBs were captured in the Section 12711 amendment discussed on page 37.

⁷ As stated in Section 25705(c), unless a specific regulatory level of a chemical listed under Proposition 65 has been established in Section 25705(b), an NSRL may be determined by the lead agency based on state or federal risk assessments.

⁸ U.S. EPA, 1996. PCBs: Cancer Dose Response Assessment and Application to Environmental Mixtures, EPA/600/P-96/001F, National Center for Environmental Assessment, Office of Research and Development, U.S. Environmental Protection Agency, Washington, DC.

⁹ Office of Environmental Health Hazard Assessment (OEHHA), 2008. Development of Fish Contaminant Goals and Advisory Tissue Levels for Common Contaminants in California Sport Fish: Chlordane, DDTs, Dieldrin, Methylmercury, PCBs, Selenium and Toxaphene, California Environmental Protection Agency, OEHHA Pesticide and Environmental Toxicology Branch, June 2008, available at: <http://www.oehha.ca.gov/fish/gtlsv/pdf/FCGsATLs27June2008.pdf>

The NSRL can be calculated from the U.S. EPA slope factor, a measure of the carcinogenic activity of PCBs, as follows. The Proposition 65 no significant risk value of 10^{-5} (representing one excess cancer case in an exposed population of 100,000 people, assuming lifetime exposure at the level in question) divided by the slope factor, expressed in units of one divided by milligrams (mg) per kilogram (kg) bodyweight per day. The result of the calculation is a dose level 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:

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

The slope factor for PCBs derived in the U.S. EPA risk assessment for food chain exposures is 2.0 per mg/kg-day. Inserting this number into the equation above results in an NSRL of 0.35 $\mu\text{g}/\text{day}$ for food chain exposures.

Section 25805(b): MADL for PCBs (food chain exposures)

OEHHA relied on a 2008 review of non-cancer endpoints conducted under its program that develops fish advisories to develop the proposed MADL.¹⁰ In addition, OEHHA conducted a search of the scientific literature to determine if more recent scientific information should be used as the basis of the MADL. No such information was identified.

As discussed in the OEHHA 2008 assessment, there are 209 possible individual chlorinated biphenyl compounds (known as congeners). Prior to their manufacture being banned in the US in 1979, PCBs were generally sold as mixtures of congeners under the trade name Aroclor. Studies of PCBs have been conducted with the specific Aroclor mixtures that were prevalent as commercial products during the period that Aroclors were actively manufactured and used. However, PCBs found in fish or other environmental media have undergone weathering that can selectively increase or decrease individual congeners, possibly increasing the overall toxicity of the mixture. Consequently, an approach that matches the expected environmental persistence and toxicity of congeners to the congener profile and toxicity of different Aroclors has been used by agencies such as U.S. EPA and OEHHA. OEHHA determined in its 2008

¹⁰ OEHHA 2008.

document that Aroclors 1260 and 1254 are the PCB mixtures that most closely approximate the environmentally persistent PCBs found in fish¹¹.

OEHHA was unable to identify any developmental toxicity studies of Aroclor 1260. A study of 1254 by Arnold et al. (1995),¹² which served as the basis for the non-cancer risk assessment in the OEHHA 2008 document, has also been identified as the most sensitive study of sufficient quality for use in deriving a MADL. In that study, female rhesus macaques were exposed orally to 0, 5, 20, 40 or 80 µg/ kg-day for 25 months prior to mating with untreated males. Dosing of the females continued throughout gestation. A statistically significantly elevated incidence of fetal mortality was reported for the highest dose group only (80 µg/kg-day). Thus, the no observable effect level (NOEL) for developmental toxicity in this study was 40 µg/kg-day.

Calculations were performed in accordance with Section 25803 to derive the MADL for PCBs using data and exposure parameters from the Arnold et al. (1995) study. The calculation of the NOEL in units µg/day is conducted by multiplying the dose in units µg/kg-day by an assumed bodyweight:

- Calculation of the NOEL dose for a 58 kg woman:
 $40 \mu\text{g}/\text{kg}\text{-day} \times 58 \text{ kg} = 2,320 \mu\text{g}/\text{day}$,
or 2,300 µg/day after rounding

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

- Derivation of the MADL from the NOEL:
 $\text{MADL} = 2,300 \mu\text{g}/\text{day} \div 1000 = 2.3 \mu\text{g}/\text{day}$

This MADL only applies to environmental mixtures of PCBs to which people are exposed via the food chain. This includes PCBs that are associated with the food chain, to which people are exposed through food consumption. This includes PCBs in meats, fish, fish oil, shellfish, eggs, dairy products, and other food products.

¹¹ OEHHA 2008, *ibid*.

¹² Arnold D.L., F. Bryce, P.F. McGuire et al. (1995). Toxicological Consequences of Arocolor 1254 Ingestion by Female Rhesus (*Macaca mulatta*) Monkeys Part 2. Reproduction and Infant Findings. *Food and Chemical Toxicology* 23(6): 457-474.

PROPOSED REGULATORY AMENDMENTS

Section 25705(c)

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

(2) The following levels based on state or federal risk assessments shall be deemed to pose no significant risk:

Chemical name	Level (micrograms per day)
Acetaldehyde	90 (inhalation)
...	
Polychlorinated biphenyls (PCBs)	0.09-0.35 <u>(food chain exposures)</u>
...	

Section 25805(b)

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

Chemical name	Level (micrograms per day)
...	
<u>Polychlorinated biphenyls (PCBs)</u>	<u>2.3 (food chain exposures)</u>
...	

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 an NSRL and a MADL, that do not require a warning or at which a discharge is not prohibited.

NECESSITY

These proposed regulatory amendments would adopt an updated NSRL and a MADL for PCBs for food chain exposures that conform to the Proposition 65 implementing regulations. The NSRL and MADL provide assurance to the regulated community that exposures or discharges at or below them are considered not to pose a significant risk

of cancer or to be less than one-thousandth of the no observed effect level for reproductive effects, respectively. Such exposures are exempt from the warning and discharge requirements of Proposition 65.

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

The 1996 U.S. EPA risk assessment provides the basis for calculating the NSRL for PCBs for food chain exposures. A copy of the 1996 U.S. EPA PCB risk assessment will be included in the regulatory record for this proposed action, and is available from OEHHA upon request. In 2008, OEHHA released a document providing the basis for fish advisories for PCBs and other compounds. The study described in that document provided the basis for calculating the MADL. That document and the study (Arnold et al., 1995) are also included in the regulatory record for this proposed action and are available from OEHHA upon request. OEHHA also relied on the attached Economic Impact Assessment in developing the proposed regulation.

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

The NSRL and MADL provide "safe harbor" values that aid businesses in determining if they are complying with the law. The alternative to the amendment to Section 25705(c) would be to not promulgate an updated NSRL for the chemical. Failure to update the NSRL would leave the public and the business community with an outdated NSRL. The alternative to the amendment to Section 25805(b) would be to not promulgate a MADL for PCBs. Failure to promulgate a MADL would leave the business community without a safe harbor level to assist them in determining compliance with Proposition 65 for the reproductive toxicity endpoint.

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 and updated NSRL 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. PCBs are listed under Proposition 65; therefore, businesses in the state must provide a warning if their products or activities expose the public or employees to this class of chemicals.

Benefits of the Proposed Regulation: The MADLs and 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 NSRLs and MADLs 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 or establishing 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 MADL and updated NSRL for PCBs (food chain exposures) 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 at or below the established level.

Reasonable alternatives to the proposed regulation: OEHHA determined that the only alternative to the proposed regulation would be to not update the NSRL and not establish a MADL for this chemical. This alternative was rejected because it would leave the public and the business community with an outdated NSRL and would fail to provide the certainty that the MADL and updated NSRL would provide.

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