

US Legislation Update

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Agency: California Office of Environmental Health Hazard Assessment (OEHHA)
<https://oehha.ca.gov/proposition-65>

Regulation: Safe Drinking Water and Toxic Enforcement Act of 1986
a.k.a. Proposition 65

Purpose: protects California's drinking water sources and informs citizens about chemicals they may come in contact with that are known to cause cancer, birth defects or reproductive harm.

Currently contains ~1000 chemicals

The Governor of California publishes the list annually.

- Naturally occurring and synthetics
- Used in manufacturing or construction or byproducts of chemical processes (e.g., automobile exhaust)
- Four mechanisms for adding to the list
 - State Qualified Experts
 - Authoritative bodies
 - Agency that requires a chemical to be labeled or identified as causing reproductive harm
 - Labor Code

Current OEHHA list available at:
<http://oehha.ca.gov/proposition-65/proposition-65-list>

Examples:

- Lead and lead compounds (car batteries, automobile paint, vinyl floor mats, auto bulbs)
- Asbestos (brake linings)
- Toluene (solvent in vehicle touch-up paint)
- Chromium and cadmium (auto paint)
- Phthalates (plasticizer additive in soft plastic components: e.g., gaskets, hoses, seat covers, steering wheel covers)

- Businesses employing less than 10 employees
- Grace period of 12 months after substance listing
- Demonstrate that exposure occurs at a level that poses no significant risk by concentrations being below Safe Harbor Numbers



- Know product composition
- Check Prop 65 list on OEHHA website to see if products contain any of the listed chemicals
 - If not, do nothing
 - If so:
 - Compare exposure levels to published Safe Harbor Numbers
 - Add warning labels as appropriate

- OEHHA develops numerical guidance levels, known as ‘Safe Harbor Numbers/Limit’
 - Safe Harbor Numbers are NOT the concentration in the product, but the maximum amount a person can be exposed to on a daily basis without requiring a warning label for the product
 - 300+ Safe Harbor Numbers established
- A warning must be given for listed chemicals if present in the product, unless the exposure is low enough to pose no human impact, i.e., at or below Safe Harbor Numbers



- Provide a Proposition 65 warning preemptively
 - OR -
- Conduct a risk assessment to establish a safe harbor number
 - Guidance for calculating Safe Harbor Number in Title 27 California Code of Regulations Articles 7 and 8
 - Based on exposure to listed substance in product
 - If carcinogen, develop no significant risk levels (NSRLs)
 - If chemical causes birth defects/reproductive harm, develop maximum allowable dose level (MADL)
 - Risk assessment must be kept in company files as supporting documentation

- Changes become effective on August 30, 2018
- In the interim, businesses may comply with the regulation in effect on August 30, 2016, or the provisions of the new regulation. Note: All products manufactured after transition period are subject to Prop 65 and will need to meet new label requirements
- Full warnings require the name of one or more of the listed chemicals to be included in the text of the warning
- Requires hyperlink to OEHHA's Prop 65 website
- Requires warning in other languages if product labeling contains information in alternate languages
- Place labeling responsibility on manufacturers, distributors, and producers for providing warnings, minimizes burden on retail sellers

“WARNING: This product contains a chemical known to the State of California to cause cancer.”

-OR-

“WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.”

- Source: C.C.R. § 25603.2



WARNING

This product can expose you to chemicals including _____, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov



WARNING

This product can expose you to chemicals including _____, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov



WARNING: Cancer -
www.P65Warnings.ca.gov



WARNING: Reproductive
Harm -
www.P65Warnings.ca.gov



WARNING: Cancer and
Reproductive Harm -
www.P65Warnings.ca.gov

- For passenger or off-road vehicles
 - Transmitted on first page or cover of owners manual – or – on front window driver's side of vehicle
 - Does not need to be permanently affixed



WARNING

. Operating, servicing and maintaining a passenger vehicle, pickup truck, van or off-highway motor vehicle can expose you to chemicals including engine exhaust, carbon monoxide, phthalates, and lead, which are known to the State of California to cause cancer and birth defects or other reproductive harm. To minimize exposure, avoid breathing exhaust, do not idle the engine except as necessary, service your vehicle in a well-ventilated area and wear gloves or wash your hands frequently when servicing your vehicle. For more information go to www.P65Warnings.ca.gov/passenger-vehicle

Enforcement of the Law

- The California Attorney General can enforce the law.
- Enforcement is typically performed by third party through litigation.
- Without a “clear and reasonable warning”, plaintiffs can sue with a reasonable suspicion that a product could lead to an exposure of a Prop 65 chemical.
 - Third party files a 60 day notice with the California Attorney General’s Office.

- Burden of proof is on the business entity
- Increased attention by third parties on labeling could potentially lead to litigation for parts not previously labeled.

- A violation generally refers to a single unit that is not appropriately labelled
- Legal action may be initiated by:
 - Attorney General (AG), district attorneys, prosecutor, etc. (10%)
 - Private citizens (90%)
- Private litigants:
 - May receive up to 25% of the civil penalties collected (plus attorney fees)
 - Number of units can be calculated from one year prior to the date of a 60-day Notice
- Non-compliance carries steep costs:
 - \$2500/day/unit for up to 1 year
 - Legal fees
 - Testing costs
 - Expert witness fees

U.S. Toxic Substances Control Act Reform
Frank R. Lautenberg Chemical Safety
for the 21st Century Act



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The New Law

- The “Frank R. Lautenberg Chemical Safety for the 21st Century Act” was signed by the President and went into effect on June 22, 2016
- Amends and updates the Toxic Substances Control Act of 1976
- Section 4 states that the EPA can require testing by order.
- Amendments to TSCA section 5 requires the EPA to make affirmative determinations on new chemicals or significant new uses of existing chemicals.
- Section 6 adds prioritization and risk evaluation steps to the process of regulating chemicals

- New chemicals will be subject to EPA review/affirmative approval before they can come to market.
- **Requires EPA to classify all “existing chemicals” as either high or low priority**
- **Requires EPA to conduct risk evaluations on all chemicals designated as high priority.**
- **EPA must take regulatory action on chemicals found to have “unreasonable risk”**
- **Finding of “unreasonable risk” must be now be based only on human health and environmental considerations (Cost and other factors may be considered for in risk management regulation).**
- EPA must consider vulnerable groups like infants, pregnant women, and the elderly.
- Requires expedited action for persistent, bio-accumulative, and toxic chemicals (PBTs)

What is new?



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- **Makes it easier for EPA to require more safety testing of chemicals.**
 - **Establishes new fees.**
 - **Pre-empts certain State regulation of chemicals on which EPA is taking or has taken action.**
 - **Establishes higher bar for regulating chemicals in articles.**
 - **Exempts replacement parts (unless EPA can show unreasonable risk).**
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EPA begins work on Chemical X:

- Determines whether Chemical X is High Priority or Low Priority
 - with public input (90 day public notice)
- If Low Priority → No further action (unless new information becomes available)
- If High Priority → Mandatory Risk Evaluation within 3 years to determine if presents “Unreasonable Risk” under intended conditions of use
 - With public input (at least 30 days public notice)
 - For each risk evaluation completed, EPA must designate a new high priority chemical
- If Chemical X determined to present an unreasonable risk then:
 - EPA must propose a risk management rule for that chemical within 1 year
 - EPA must issue final risk management rule within 2 years (with potential 2 year extension except for TSCA Work Plan chemicals or chemicals that score high for persistence or bioaccumulation.) to restrict that chemical
 - Risk management options under Sec. 6 are broad and include labeling, use restrictions, phase-outs/bans

- Articles
- Replacement Parts

Section 5(a)(5) – SNURs for articles – EPA may apply Significant New Use Rules to articles only to the extent necessary to protect against risks from exposure to the SNUR chemical from articles.

“(5) ARTICLE CONSIDERATION.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.”

Section 6(c)(2)(E) – Articles – EPA may apply risk management rules to chemicals in articles only to the extent necessary to protect against risks from exposure to the chemicals from the articles.

“(E) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or the category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).”

Section 6(c)(2)(D) – Replacement parts – The risk management rule must exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication of the final rule, unless EPA finds replacement parts contribute significantly to the risk.

“(D) REPLACEMENT PARTS.—

(i) IN GENERAL.—The Administrator shall exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation conducted under subsection (b)(4)(A), to the general population or to an identified potentially exposed or susceptible subpopulation.

(ii) DEFINITIONS.—In this subparagraph—

the term “complex consumer goods” means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace; and the term “complex durable goods” means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use.”

Selected EPA Action Dates Under New TSCA



EPA Action	Proposed	Final
Publish list of first 10 chemicals to be risk evaluated (from Work Plan chemicals)	Dec 2016	
Develop 1st Annual Plan for Risk Evaluations (list chemicals to be evaluated) [Within 3.5 years, EPA must have evaluations underway for at least 20 high priority chemicals]		Jan 2017
Publish Scopes of Initial 10 Chemical Risk Evaluations		June 2017
Prioritization Process Rule (to establish criteria for designating high & low priority chemicals)	Dec 2016	June 2017
Risk Evaluation Process Rule (process for risk assessing high priority chemicals)	Dec 2016	June 2017
Fees Rule	Dec 2016	June 2017

Selected EPA Action Dates Under New TSCA



EPA Action	Proposed	Final
Inventory Rule (reporting of chemicals manufactured/processed in past 10 years)	Dec 2016	June 2017
Establish Science Advisory Committee on Chemicals	Sept 2016	June 2017
Mercury – Additions to existing mercury export ban		Sept 2016
Mercury – First Triennial Inventory of mercury supply, use and trade in U.S.		Apr 2017
Final rules for Trichloroethylene, NMP & Methylene Chloride		Dec 2017
Mercury Use /Product Reporting Rule		Jun 2018
Processor reports due for inventory reset: active substances list		Jun 2018
CBI Review/Substantiation Rule		Jun 2018

Selected EPA Action Dates Under New TSCA



EPA Action	Proposed	Final
Final Rule for review of the confidential chemicals on the active substances list		Dec 2018
Propose rules on certain PBT's	Jun 2019	
Ensure that risk evaluations are underway for the 20 high priority chemicals]	Dec 2019	
Ensure that 20 low priority chemicals are designated	Dec 2019	
Final rules for Trichloroethylene, NMP & Methylene Chloride		Dec 2017

- For more information from Office of Environmental Health Hazard Assessment (OEHHA)
<https://oehha.ca.gov/proposition-65>
- Chemicals under the Toxic Substances Control Act (TSCA) <https://www.epa.gov/chemicals-under-tsca>
- IMDS Conference, September 26-27

THANK YOU!