

WARNING – California Proposition 65 Requirements are Changing - Are You Ready ? / J-2/25

Presented by

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WARNING – California Proposition 65 Requirements are Changing - Are You Ready?

Agenda:

- > What is Proposition 65?
- > Recent Changes to Prop 65 Warning Requirements
- > Testing/Exposure Assessment for Listed Carcinogens and Reproductive Toxins
- > Safe Harbor Language and Text Requirements
- > Communicating "Safe Harbor" Warnings
- Public Entrance Warnings
- Accessibility and Locations for Warnings
- > Short Form Warnings
- Requirements for Signs
- > Languages other than English
- Environmental Exposures and Warnings
- Occupational Exposures and Warnings
- > Tailored Warnings
- Enforcement of Prop 65 Requirements



California Prop 65 Update

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Learning Outcomes

Upon completion, participants will be able to:

- > Recognize potential exposures to Prop 65 listed carcinogens and reproductive toxins and evaluate exposures with respect to NSRL and MADL thresholds
- > Identify applicable Prop 65 requirements for consumer, environmental and occupational exposures
- > Develop warnings for potential exposures that meet prop 65 requirements to provide "clear and "reasonable" warnings through "Safe Harbor" language



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What is Proposition 65?

- Safe Drinking Water and Toxic Enforcement Act of 1986.
- Requires businesses to warn Californians about "significant" exposures to chemicals that cause <u>cancer</u>, birth defects or other <u>reproductive harm</u>.
 - In products, homes or workplaces, or released to the environment.
 - Also prohibits California businesses from knowingly discharging significant amounts of listed chemicals into sources of drinking water.
- > Requires Cal/EPA Office Environmental Health Hazard Assessment (OEHHA) to publish a list of chemicals that cause cancer, birth defects or reproductive harm.
 - This list has approximately 900 chemicals.
- Intended to provide information and allow individuals to act accordingly



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New Regulations

- > OEHHA updated Prop 65 warning regulations, effective August 30, 2018
 - Title 27, California Code of Regulations
 - Based on concerns that warnings were too general, not informative
 - Original proposal required specific exposure assessment
- Mandatory provisions and non-mandatory, "safe harbor" methods for "clear and reasonable" warnings.
- In general, specific warnings are required, compared to previous "blanket" warnings
- > Warning method & requirements depend on type of exposure
 - Consumer product, Environmental, Occupational, "Tailored"



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Effective Dates

- > New warnings become operative August 30, 2018 (prior 2008 safe harbor warning methods will no longer be operative).
- > Consumer products manufactured before August 30, 2018 and labeled with a 2008 compliant warning do not require a new warning.
 - Also products covered by court-approved settlements
- > Manufacture date determines whether the product should have a new warning (not sales date)



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When are Warnings Required



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Requirement for Warnings

- Businesses must provide warnings for potential exposures to listed substances over threshold levels
 - Exposure assessment, and requirement for warnings, is up to business
 - Regulations do not require testing
- > OEHHA has threshold "Safe Harbor" levels for 300+ Proposition 65 chemicals.
 - Level of exposure to listed chemical that does not require Proposition 65 warning.
 - NSRL No Significant Risk Levels, chemicals listed as causing cancer
 - MADL Maximum Allowable Dose Levels for chemicals listed as causing birth defects or other reproductive harm.



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What is on the List?

https://oehha.ca.gov/proposition-65/proposition-65-list:

- Acrylamide (in roasted/fried foods) C/R
- > Alcoholic Beverages C
- Aloe Vera (whole leaf extract) C
- > Aspirin R
- > Benzene (fuels) C/R
- > Carbon Monoxide (combustion) R
- Gasoline exhaust C
- Marijuana/Tobacco Smoke C/R
- > Salted Fish (Chinese style) C
- > Toluene Diisocyanate C
- Wood Dust C



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General Types of Listed Substances

NOT a complete list!

- > Metals (various)
 - Antimony, Arsenic, Beryllium, Cadmium, Chromium, Lead, Mercury, Nickel
- > Antibiotics
 - Amicacin, Abimectin
- > Pesticides/Herbicides
 - Aldrin, Chlordane, Chlorpyrifos, DDD/DDT, Dieldrin, Malathion
- > Chemotherapy
 - Carboplatin, Chlorozotocin, Cisplatin, Etoposide, Fluorouracil, Methylthiouracil, Paclitaxel
- > Hormones and related
 - Anabolic steroids, DES, Estrogens/Estradiol, Lynestrenol, Norethisterone
- Many other "usual suspects"!



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Consumer Exposure Assessment

- > Evaluate total exposure (in μg/day) by all routes of exposure (dermal, ingestion, inhalation)
 - Based on exposure assessment assumptions Exposure per use, exposure scenarios
 - Compare to NSRL/MADL
- Exposure Scenarios for most consumer products not well defined
 - How is product actually used? How could it be used? What is worst-case?
- Most businesses assume potential exposures >NSRL/MADL if product contains listed chemicals

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Occupational/Environmental Exposures

- > Closer to traditional IH exposure assessment
 - Exposure scenarios more limited, but exposure limits are very low!
- \rightarrow Lead exposure at the PEL (50 μ g/m³) = 500 1000 μ g/day
 - Based on breathing rate of 10 m³ 20 m³/day
- > Lead MADL = 0.5 μg/day
 - \circ 5 10 µg/day, 0.05 0.025 µg/m³
- > IH sampling requires 1500 liters, based on LOD of ICP/MS of 0.075 μg
 - \circ 0.075µg/1.5 m³ = 0.05 µg/m³
 - Equivalent to 480 minutes at 3.125 l/m
 - Not impossible, but that's a lot of air!
- And what about dermal??



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Safe Harbor Language

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Safe Harbor Language

- > If potential exposures exist, "safe harbor" language provides adequate warnings
- > Safe harbor warning methods and content are considered to be "clear and reasonable" and provide a "safe harbor" against enforcement if businesses use them.

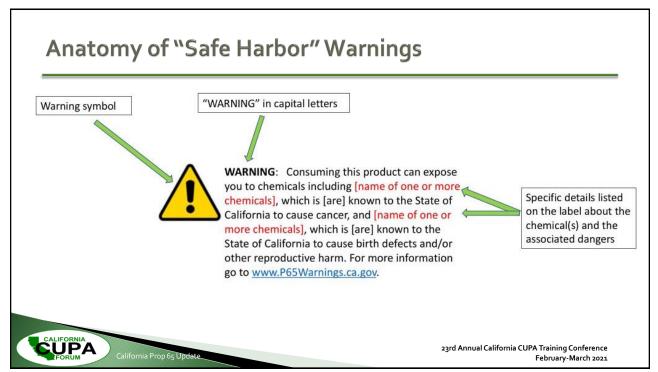
WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

• Business can choose to use other methods; however, the business might have to defend the warning if it were challenged by a public or private enforcer as not being clear and reasonable



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Safe Harbor Symbol & Type Size

- Warning Symbol must be yellow
 - Business may print the symbol in black and white if it does not use yellow for other information on the label or sign
- > No specific type size requirement.
- > Consumer product warnings on a labels must be:
 - "Prominently displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning likely to be seen, read, and understood by an ordinary individual under customary conditions of purchase or use."



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Examples of Acceptable Warning Labels Under the New Regulations

Cancer



WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information, visit www.P65Warnings.ca.gov.

Combined Cancer/Birth Defect



WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer or birth defects or other reproductive harm. For more information, visit w w.w. P65 Warnings.

Birth Defect



WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information, visit www.P65Warnings. ca.gov.

Truncated on Product Warning



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

Type Size: The warning text must be the same size as other consumer information presented on the package and may not be smaller than 6-point type.

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Providing Warnings

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Who should provide a warning?

- Manufacturers, producers, packagers, importers, suppliers or distributors have primary responsibility for providing consumer product warnings.
- Manufacturers (and others) must either provide a warning on the product label or provide notice and warning materials to "the authorized agent" for a retail seller and receive an acknowledgment that the notice was received
- Retail sellers are responsible for placement and maintenance of the warning materials received from manufacturers, producers, packagers, importers, suppliers or distributors



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"Upstream" Manufacturers

- Consumer product manufacturer that do not sell directly to retailers have two options for compliance:
 - Providing warning on the product label or
 - Providing written notice warning is required and warning materials (such as shelf signs) to packager, importer, supplier
- Manufacturers and others in supply chain should ensure warnings are passed to retailer and ultimately consumers
 - For example manufacturer/producers may enter into a contract with businesses along chain of commerce and/or retailer to ensure warnings are transmitted to the retailer and consumer



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Bulk Commodity Manufacturers

- Consumer warnings required if the end use of the component or ingredient can expose consumers to a listed chemical
 - If ingredient manufacturer knows use in prepared foods could result in consumer exposures, they should provide warnings to product mfg.
 - Product mfg. is then responsible for determining if the product causes an exposure requiring a warning, and providing warnings
- Bulk mfg. can work with product manufacturers to determine if the product requires a warning and may enter into contract with the mfg. to transmit warnings to retailer and consumer
- Manufacturers of parts or ingredients that include listed chemicals may also need to provide occupational or environmental warnings



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Providing "Safe Harbor" Warnings

Four options for consumer product "Safe Harbor" warnings:

- Product-specific warning on a sign, shelf tag, or shelf sign, at each point of display of the consumer product.
- 2. Product-specific warning automatically provided by an electronic device warning purchaser before purchase without requiring the purchaser to seek the warning.
- 3. Warning on label complying with in Section 25603(a);
 - Warning symbol, signal word, "WARNING:" and applicable message.
- 4. Short-form warning on label complying with 25603(b);
 - Warning symbol, signal word, "WARNING:" and applicable truncated message. Type must be no smaller than largest type used for other consumer information on product, minimum 6-point type.



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Internet & Catalog Sales

- > Website warnings can use short-form warning content, may also use a picture of the label on the product
 - See Questions and Answers for Businesses: Internet and Catalog Warnings" on Prop 65 site



Public Entrance Warnings

- Safe harbor warnings must be clearly associated with the product that is the subject of the warning and comply with the other requirements
- > Standalone warnings at public entrances intended to address all possible consumer product exposures are no longer acceptable
- > Not considered "Safe harbor warning"

WARNING

This Facility Contains
Chemicals Known To
The State Of California
To Cause Cancer And
Birth Defects Or Other
Reproductive Harm



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Toy Car Replica Vehicle Scenario

- Your (California-based) company manufactures highly detailed replicas of unique performance vehicles (they're not toys!)
 - Your version of the Saleen S7 Turbo uses real "beryllium orange" paint, which contains approximately 1% beryllium (by weight) to achieve a unique metallic effect that is popular with collectors
 - Beryllium and beryllium compounds are on the OEHHA Prop 65 list for carcinogenicity





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Warning Requirements



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Warning Requirements

- > Type (font) size requirements depend on the category of exposure
- Consumer product warnings must be prominently displayed on label, labeling, or sign:
 - "Must be displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning likely to be seen, read and understood by an ordinary individual under customary conditions of purchase or use"
- > Some safe harbor warnings have minimum type size.
 - Short-form warnings for consumer products, Environmental exposure warnings, some "tailored warnings"



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Warning Label Location

- Warning may be provided on exterior packaging or label
- "Label" is a "display of written, printed or graphic material printed on or affixed to a product or its immediate container or wrapper"
 - Placed to ensure consumers receive the warning prior to exposure.
 - Visible on opaque exterior packaging if exposure requiring a warning can occur upon opening the package
- > Standalone warning in an owner's manual is not acceptable
 - Owner's manuals are included as part of a warning method for diesel engines, passenger vehicles and recreational vessels, with other warnings



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Short Form Warning

- Business may use standard or short-form warning content on a "label" for a consumer product exposure
 - Not applicable to "signs"
- > Short-form is alternative for small products or where space was limited but can be used on larger products.
- Must use type no smaller than the largest type size used for other "consumer information", minimum 6-point
 - Consumer information includes directions for use, ingredient lists, etc. Does not include brand name, name, company name, advertising, etc.
- > Short-form warning can be provided on product "label", including immediate container or wrapper



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"WARNING: Cancer – www.p65warnings.ca.gov"



"**WARNING:** Reproductive Harm – www.p65warnings.ca.gov"



"**WARNING:** Cancer and Reproductive Harm – www.p65warnings.ca.gov"



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Chemical Names

- > For Safe Harbor, warnings must include at least one chemical
 - Chemicals listed as they appear on the Proposition 65 list. If abbreviation is included, the abbreviation can be used.
- > For multiple potential carcinogen (or repro toxin) exposures from a product, the business is only required to name one
 - Businesses may identify the others.
- > For exposures to carcinogens & reproductive toxicants, businesses must name one of each
 - Businesses may identify more.
- If warnings include carcinogen and reproductive toxicants, warning only needs to name one chemical but both endpoints must be included in the warning.



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Languages other than English



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- If consumer information is provided in a language other than English, warnings must also be provided in that language
- If signage at a business or facility is in a language other than English, then environmental warnings must also be in that other language
- Prop 65 warnings are translated into Spanish,
 Cambodian, Chinese (traditional and simplified),
 French, Hmong, Korean, Tagalog and Vietnamese.

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Environmental and Occupational Warnings



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Environmental Exposures

- All exposures that are not consumer product or occupational exposures are environmental exposures.
- "Safe Harbor" warnings must be provided if visitors can be exposed above NSRL/MADL
 - Businesses must determine if there is an exposure to a listed chemical Warnings not required for "presence"
- > Must be conspicuous and close to source of exposure
 - Must describe areas for the chemical(s) named in the warning.
 - Warning for multiple chemicals and/or multiple exposures must describe areas where exposures could occur
- > May be needed in more than one location for warning(s) to be clearly associated with the source(s) of exposure.



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Transmitting Environmental Warnings

Three Methods:

- Signs that identify sources of exposure in conspicuous location at public entrances to affected area
 - For spaces with defined entrances,
 - 72-point type, in English and other language used on other signage
- 2. Notices mailed, sent electronically, or delivered to each occupant in the area.
 - Must identify sources of exposure, including a map of affected area,
 - provided at least every 3 months, in English and in any other language ordinarily used by the person



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Transmitting Environmental Warnings

- Warnings published in newspaper with largest circulation in the area, at least every 3 months.
 - Must identify sources of exposure,
 - At least a ¼ page, including a map of the affected area
 - Must also be published in electronic version of publication, if any.
 - If a newspaper published in a language other than English is circulated in the affected area, the warning must be published in that newspaper and in that language, in addition to at least one English-language newspaper that in that area.



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Environmental Warnings

For indoor environments or outdoor spaces with clearly defined entrances, a warning sign must be posted at all public entrances to the affected area in no smaller than 72-point type:

▲ WARNING: Entering this area can expose you to [name of chemical] from [name of one or more sources of exposure]. [Name of chemical] is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

▲ WARNING: Entering this area can expose you to chemicals known to the State of California to cause cancer and birth defects or other reproductive harm, including [name of one or more chemicals known to cause cancer and name of one or more chemicals known to cause birth defects or other reproductive harm], from [name of one or more sources of exposure]. For more information go to www.P65Warnings.ca.gov.



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Location of Environmental Warnings

- For exposures throughout a facility, like exposures to a solvent used throughout a large art studio, a warning at the entrance naming the chemical and the source (paint) may be appropriate.
- A warning at the entry of a facility for an exposure likely to occur in one area, such as in an art studio on the 3rd floor of a building, would not be associated with the exposure

Warning Entering this area can expose you to chemicals known to the State of California to cause cancer and birth defects or other reproductive harm, including [name of one or more Listed Chemical(s)], from [name of one or more sources of exposure]. For more information go to www.P65warnings.ca.gov



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Occupational Exposures

- > Warnings must be provided if workers are exposed above NSRL/MADL
 - Complying with HazCom and Pesticide Applicator training and warning requirements satisfies
 Prop 65 occupational warning requirements
 - Listed chemicals must be specifically addressed
- > Proposition 65 warning may be required for occupational exposures to a listed chemical not addressed under HazCom
- Businesses can also use safe harbor warning methods and content for occupational exposure to a listed chemicals
- SDS may be used to provide occupational exposure warnings only, they are not a safe harbor warning method for other consumer product or environmental exposures



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"Tailored" and Special Warnings

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Tailored Warnings - Products

- > Alcoholic Beverages
- Diesel Exhaust
- > Furniture Products
- > Passenger & Off-Highway Vehicles
- > Recreational Vehicles
- > Wood Dust

Warnings are only required only when there is an exposure to a listed chemical from the product.

https://www.p65warnings.ca.gov/sample-warnings-and-translations-businesses



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Alcoholic Beverages Exposure Warnings

- > For 8 ½ x 11 sign, alcoholic beverage warnings must be no smaller than 22-point type
 - For 5 x 5 sign, warnings must be no smaller than 20-point type and enclosed in a box.
- For alcoholic beverages sold or distributed through package delivery services, warnings must be in a type size no smaller than the largest type size used for other consumer information on the product,
 - In no case smaller than 8-point type.

WARNING: Drinking distilled spirits, beer, coolers, wine and other alcoholic beverages may increase cancer risk, and, during pregnancy, can cause birth defects. For more information go to www.P65Warnings.ca.gov/alcohol.

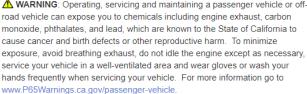


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Passenger and Off-Highway Vehicles Exposures

A vehicle exhaust warning provided in the owner's manual must be in no smaller than 12-point type and enclosed in a box AND the warning label be attached to the driver's side front window.





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Wood Dust Exposure Warnings

- > Point of sale or display warnings must be no smaller than an 8½ by 11 inches sign, using no smaller than 20-point type.
- > When product is sold in bulk, warnings may be provided on invoice or receipt using no smaller than 12-point type.



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Tailored Warnings - Places

- > Amusement Parks
- Dental Offices
- Designated Smoking Areas
- Enclosed Parking Facilities
- Hotels
- Petroleum Products Environmental
- Restaurants
- Service Stations
- Vehicle Repair Facilities

Warnings are only required only when there is an exposure to a listed chemical from the product.

and-translations-businesses



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https://www.p65warnings.ca.gov/sample-warnings-

Amusement Park Exposure Warnings

The amusement park warning must be posted at each public entrance in no smaller than 72-point type.

▲ WARNING: Some areas or features in this amusement park can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer or birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/amusement-parks.



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Designated Smoking Areas

- > 8 ½ by 11 inches sign
- > Posted at entrance and within the exposure area,
- > No smaller than 22-point type, enclosed in a box





Breathing the air in this smoking area can expose you to chemicals including tobacco smoke and nicotine, which are known to the State of California to cause cancer and birth defects or other reproductive harm.

Do not stay in this area longer than necessary.

For more information go to www.P65Warnings.ca.gov/smoking-area

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Hotel Exposure Warnings

Safe harbor warnings for exposures to listed chemicals at hotels/ lodging establishments may be provided by:

- A sign at the registration desk where it will be likely to be seen, read, and understood prior to the completion of the registration or check-in process
 - No smaller than 22-point type.
- 2. Provided electronically to guest (directly or via a hyperlink) or in hard copy,
 - Same size/type as other consumer information prior to, or during the registration or check in process.



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Enclosed Parking Facility Exposure Warnings

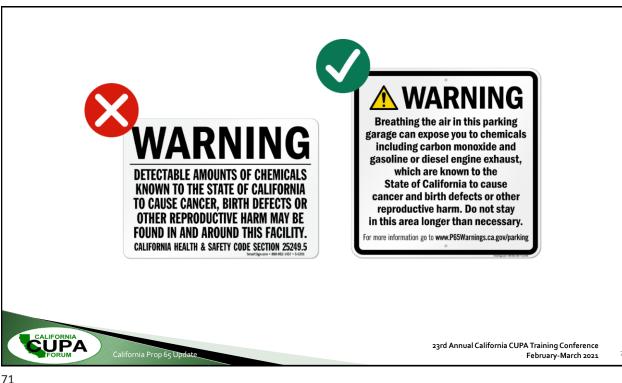
> 20 by 20 inch sign at each public entrance, no smaller than 72-point type.

▲ WARNING: Breathing the air in this parking garage can expose you to chemicals including carbon monoxide and gasoline or diesel engine exhaust, which are known to the State of California to cause cancer and birth defects or other reproductive harm. Do not stay in this area longer than necessary. For more information go to www.P65Warnings.ca.gov/parking.



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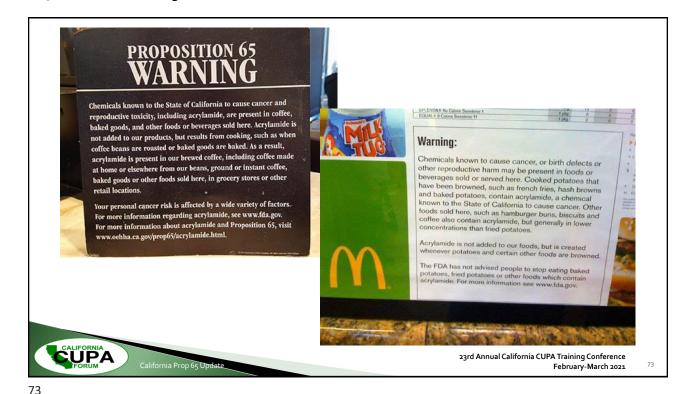
Food and Non-Alcoholic Beverage Exposure Warnings for Restaurants

- > 8½ by 11 inches sign, no smaller than 28-point type, at each public entrance where food or beverages are consumed or
- > 5 by 5 inches sign, no smaller than 20-point type or
- On the menu or list describing food or non-alcoholic beverages
 - Type size no smaller than largest type size used for general menu items.



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Service Station Environmental Exposure Warnings

> Posted on each gas pump, printed in no smaller than 22-point type, and enclosed in a box.



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Multiple Exposures

- > Multiple types of warnings for multiple types of exposures
 - Example Amusement parks warnings at public entrances, additional warnings for consumer products, alcoholic beverages, food, and enclosed parking facilities
 - Combining multiple warnings into one warning message would generally not meet safe harbor requirements.
- > Example vehicle repair facility that allows smoking-
 - Warnings for exposure to petroleum products and for tobacco smoke
- > Safe harbor elements for each must be included
 - Combined sign would need to be 8 ½ by 11 (smoking area requirement),
 - Posted at each public entry and in smoking area
 - No smaller than 32-point type (repair facility requirement)
 - Messages enclosed in boxes to satisfy the safe harbor requirements.
- > Simpler to provide separate warnings using the applicable methods and content.



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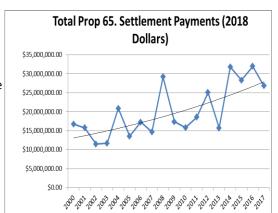
Enforcement of Proposition 65



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Enforcement

- > Enforced by State Attorney General,
 - Californians can also sue if they believe a violation has occurred
 - Fines of up to \$2,500 per day per violation (plus attorney's fees).
 - Reforms to limit predatory lawsuits include disclosure and certificates of merit
- Private enforcement is a multi-million dollar enterprise
 - Plaintiffs frequently attorneys or "environmental" groups.
- Settlement frequently "payment in Lieu penalty"
 - Bounty hunters only get 25% of penalties recovered;
 no limit on attorney fees



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Public Enforcement

- California Attorney general, any district attorney, and any city attorney of a city with 750,000 residents may bring a suit.
 - Or any person can bring a Prop 65 claim "in the public interest"
- > "60 day" Notice
 - Private enforcer must notify AG
 - Unless public enforcer "has commenced and is diligently prosecuting an action" in 6o days, lawsuit may proceed
- Requires "certificate of merit"
 - One or more persons with relevant and appropriate experience or expertise who has reviewed facts, studies, or other data regarding the exposure to the listed chemical"
 - The person executing the certificate believes there is a reasonable and meritorious case for the private action."



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Options to Defend Against Lawsuits

- Settle the Lawsuit (or "payment in lieu of penalty")
 - Injunction, penalties, attorney fees
 - Defendant liable for attorneys' fees (incentive to settle)
- 2. Fight the lawsuit
 - "Safe Harbor" defense show exposures will not exceed NSRL/ADL
 - Based on average user, not mis-use or out-of-ordinary use
 - Requires expert witnesses, exposure assessment, etc. -
 - Expensive Cases seldom make it to court
- Fight the toxicology
 - Show toxicology basis is invalid or does not apply
 - Complex & expensive used by larger companies, industries



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So What Should a Company Do?

Be Knowledgeable:

- > Understand product & formulation
 - Do potential exposures exist?
- Understand potential exposures
 - If possible

Be prepared:

- Provide applicable warnings
 - Consumer, environmental, occupational, "tailored"
 - Don't be a soft target

Be Responsive:

Use an experienced Prop 65 attorney to aggressively defend yourself if you receive notice



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