

# UPDATE ON CALIFORNIA PROPOSITION 65

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**Presented by:**

Gary Whitmyre, D.A.B.T., toXcel LLC (Virginia)

Jon Benjamin, Esq., Farella Braun + Martel LLP (California)



# UPDATE ON CALIFORNIA PROPOSITION 65

## OUTLINE:

1. Background On Proposition 65
2. Toxicology, Exposure Assessment, Risk Assessment
3. Enforcement
4. New Warning Requirements
5. The “Naturally-Occurring-in-Food” Exemption Strategy
6. Recent Chemicals of Interest
7. Take-Aways
8. Questions and Discussion

# CALIFORNIA PROPOSITION 65: BACKGROUND

## LEGAL/ADMINISTRATIVE STRUCTURE:

- Voter-passed ballot initiative in 1986 (requires a 2/3 vote in the State Assembly and State Senate to amend).
- Administered by Office of Environmental Health Hazard Assessment (OEHHA), which is part of the California EPA
- **Public** enforcement by California AG and District Attorneys
- **Private** enforcement by private “bounty hunters”
- Focuses on exposures to listed carcinogens and developmental/ reproductive toxicants
- Intent is to force reformulation

# CALIFORNIA PROPOSITION 65: BACKGROUND (CONTINUED)

## LEGAL/ADMINISTRATIVE STRUCTURE (continued):

- OEHHA maintains lists, which are updated at least annually
- OEHHA issues regulations and develops regulatory benchmarks
- Timeline: Listing, Risk Assessment, Warnings
  - Proposal to list
  - Comment period
  - Listing
  - Risk assessment
  - Evaluate and implement compliance options
- Proposition 65 Discharge Ban not part of today's presentation
- Occupational exposures: pre-emption and resolution

# CALIFORNIA PROPOSITION 65: BACKGROUND (CONTINUED)

## HOW DOES THIS CHANGE THE REGULATORY LANDSCAPE?:

- Proposition 65 *shifts* the burden of proving the safety of exposures to chemicals in products from government *to industry*.
- Proposition 65 is an *exposure-based* and *risk-based* regulatory program.
- Proposition 65 requires legally-mandated “clear and reasonable” *warnings* for exposures to chemicals in products that exceed risk-based benchmarks.
- There are *other compliance options*, e.g., product reformulation
- Successfully addressing the challenges of Proposition 65 for your product(s) depends on both *legal* and *scientific* defenses.

# CALIFORNIA PROPOSITION 65: BACKGROUND (CONTINUED)

## PROPOSITION 65 CHEMICAL LISTS:

- Approximately 900 chemicals listed.
- OEHHA Promulgated NSRLs: < 300 Chemicals (April 2017)
- OEHHA Promulgated MADLs: < 40 Chemicals
- NSRLs and MADLs NOT developed for 60% of listed chemicals.
- Development of these benchmarks is allowed where OEHHA has not done so, or where regulated parties disagree with OEHHA's NSRLs and MADLs [27 CCR §25701].

# CALIFORNIA PROPOSITION 65: BACKGROUND (CONTINUED)

## REGULATORY BENCHMARKS:

- **The No-Significant-Risk-Level (NSRL)**

is the long-term average exposure that corresponds to an excess cancer risk of  $10^{-5}$  (1 excess cancer case in population of 100,000 individuals).

- **The Maximum-Allowable-Dose-Level (MADL)**

is the “per-day” allowable exposure to a reproductive/developmental toxicant that is 1000-fold less than NOAEL.

# CALIFORNIA PROPOSITION 65: BACKGROUND (CONTINUED)

## REGULATORY BENCHMARKS -- CARCINOGENS:

- The NSRL is developed from dose-response modeling of cancer potency.
- Results of dose-response modeling can be expressed as the cancer potency factor, also known as the “slope factor” or  $q_1^*$  in units of risk per mg/kg/day dose.
- Alternatively, the dose-response can be expressed as the dose producing a  $10^{-5}$  risk (i.e., 1 excess lifetime case of cancer per 100,000 exposed persons). This is known as the LED  $10^{-5}$ .
- Either the  $q_1^*$  or the LED  $10^{-5}$  can be used to calculate the NSRL.



# CALIFORNIA PROPOSITION 65: BACKGROUND (CONTINUED)

## REGULATORY BENCHMARKS -- REPRO/DEVELOPMENTAL:

- The MADL is developed from dose-response (animal studies).
- The “Point of Departure” for the risk assessment is the No-Observed-Adverse-Effect-Level (NOAEL).
- The MADL is the NOAEL divided by a 1000-fold Safety Factor.

# CALIFORNIA PROPOSITION 65: BACKGROUND (CONTINUED)

## REGULATORY FRAMEWORK:

- Proposition 65 presents a very conservative regulatory framework
- Risk benchmarks based on rigorous risk-based standards
- Can go beyond this to refine the risk assessment using scientifically defensible risk assessment approaches
- Key is to understand how OEHHA would do it and improve on it
- You must be prepared to defend your assumptions and methodology
- Data-based approach (e.g., product use information)
- This is where the science and legal come together

# CALIFORNIA PROPOSITION 65: RISK ASSESSMENT

## KEY POINTS:

- Exposure/risk assessment determines whether warning is needed for certain product use scenarios.
- Focus on the “**typical anticipated use**” rather than the “worst-case”.
- Allows the use of alternative standards, exposure parameters, and risk assessment methods if scientifically defensible [27 CCR §25900, §25703, §25721].
- For risk assessment purposes, “non-detects” are assigned a value of the limit of detection for the specific chemical in the product.

# CALIFORNIA PROPOSITION 65: RISK ASSESSMENT (CONTINUED)

## ROUTES OF EXPOSURE FOR LIQUID PRODUCTS, AS EXAMPLE:

- Applicator dermal exposure during dilution and use
- Inhalation exposure to VOCs and SVOCs during application
- Inhalation exposure to fine particles and aerosols (applicators)
- Post-application secondary dermal contact with cleaned surfaces
- Post-application ingestion exposures from food contact surfaces
- Post-application inhalation exposure to VOCs and SVOCs
- Hand-to-mouth exposures from cleaned surfaces (toddlers), if relevant to product

# CALIFORNIA PROPOSITION 65: RISK ASSESSMENT (CONTINUED)

## THE ADVANTAGES OF A RISK ASSESSMENT:

- Risk assessment determines if NSRL or MADL exceeded.
- If exposures < NSRL and <MADL, this becomes bargaining chip in settlements, and is part of your litigation defense.
- Risk assessment can:
  - Show good faith effort
  - Reduce settlement costs
  - Buy time for re-formulation
- Not required to warn if risk assessment demonstrates applicable NSRLs and MADLs are not exceeded (the safe harbor exemption)
- Risk assessments are not filed with OEHHA or AG

# CALIFORNIA PROPOSITION 65: EXPOSURE ASSESSMENT

## ITERATIVE APPROACH TO EXPOSURE ASSESSMENT:

- If  $LADD > NSRL$ , or  $E_{\text{daily}} > MADL$ , you should not stop here.
- Instead, the next step is to refine exposure assessment, for example:
  1. Physiologically-based inhalation rates (e.g., per the USEPA's Exposure Factors Handbook);
  2. Consideration of dermal absorption, based on literature data or estimation methods (e.g., per the USEPA's dermal exposure assessment guidance document);
  3. Updated hand-to-mouth (HTM) exposure assessment methods for toddlers having post-application contact with cleaned surfaces, if relevant to product.

# CALIFORNIA PROPOSITION 65: EXPOSURE ASSESSMENT (CONTINUED)

## SAFE USE DETERMINATION:

- Manufacturer can request that OEHHA conduct a “Safe Use Determination” to define the maximum “safe” level of a Proposition 65 chemical in a specific type of product for a specific type of use.
- CAUTIONS:
  - No control over assumptions and methods used by OEHHA;
  - May not include appropriate method refinements;
  - No control over NSRL or MADL value(s) used by OEHHA;
  - Can be costly and time-consuming
  - Results are made public.

# CALIFORNIA PROPOSITION 65: ENFORCEMENT

## **BACKGROUND:**

- Statute allows for civil penalties of \$2,500 per day per violation.
- For consumer products, each exposure to that product is a violation.
- One-year Statute of Limitations on Penalties
  - going back one year from the date complaint filed in court
  - going forward until resolution (court judgment, warning, reformulation)
- In reality, penalties in settlement will not be close to high-end of possible fines.



# CALIFORNIA PROPOSITION 65: ENFORCEMENT (CONTINUED)

## BACKGROUND (continued):

- Settlements or judgments can include injunctive relief.
- Under injunctive relief, e.g., you agree to do X, you won't do Y, and Court or Plaintiff(s) can enforce these agreements.
- California AG and DAs can bring enforcement actions.
- Private bounty hunters may too, but must give a 60-day notice of intent to file a lawsuit to allow the AG and/or DAs sufficient time to decide whether they will take over the case and remove bounty hunters from the case.

# CALIFORNIA PROPOSITION 65: ENFORCEMENT (CONTINUED)

## “BOUNTY HUNTER” GROUPS:

- Highlighting a bounty hunter group:
  - Center for Environmental Health (CEH)
  - In 2010, collected almost \$7 million in penalties\*
  - Only small fraction of settlements goes to the state
  - This has become a big issue for the California AG.
- Basis for bounty hunter strategy:
  - Based on chemicals in raw materials and products
  - Amount in product does not matter
  - Ignores importance of exposure in assessing actual risk
  - Stated goal is removal of chemical from product
  - Defendant’s complaints re: perceived “extraction” of money.

\* AT Caso. (2012). *Federalism & Separation of Powers. Bounty Hunters and the Public Interest – A Study of California Proposition 65*. Engage 13 (1): 30-37.

# CALIFORNIA PROPOSITION 65: ENFORCEMENT (CONTINUED)

## COSTS OF PROPOSITION 65 LAWSUITS TO INDUSTRY:

- Between 2000 and 2010, more than **\$142 million** paid in settlements\*
- Does not include legal costs imposed on business
- Does not include opportunity costs
- Does not include costs of cases that actually went to trial
- The California Attorney General has collected just **15 %**\* of the total settlement money, on average
- About **85 %** goes to the bounty hunter groups and their attorneys
- Enforcement of Proposition 65 by bounty hunters is subject to abuse
- AG can take role in policing abuses, but generally only for worst cases

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\* AT Caso. (2012). *Federalism & Separation of Powers. Bounty Hunters and the Public Interest – A Study of California Proposition 65*. Engage 13 (1): 30-37.

# CALIFORNIA PROPOSITION 65: ENFORCEMENT (CONTINUED)

## ATTORNEY GENERAL'S NEW REGULATORY AMENDMENTS:

- Adopted August 2016 to curb perceived litigation and settlement abuses by bounty hunters.
- Civil penalties may not be traded for payment of attorney's fees or create new requirements when settlement terms waive civil penalties due to defendant's conduct.
- Plaintiffs must demonstrate that any "Additional Settlement Payments" made to Plaintiffs or Third Party as offset to civil penalties are in the public interest.
- Requires showing "significant" public benefits derived from settlement.
- Requires public benefits established by product reformulation, including demonstrable reduction in exposure in lieu of warning.

# CALIFORNIA PROPOSITION 65: ENFORCEMENT (CONTINUED)

## ATTORNEY GENERAL'S NEW REGULATORY AMENDMENTS (continued):

- Regarding settlement terms:
  - Where private party enters settlement in the absence of a filed judicial complaint, plaintiff must serve AG with settlement and accompanying form, "Report of Settlement"
  - Parties are encouraged to submit all settlements that include "Additional Settlement Payments " for judicial review
- Modify guidelines addressing recovery of plaintiff's attorney fees by:
  - Requiring showing that public benefits derived from settlement are "significant"
  - Making presumption rebuttal that public benefit is established by product reformulation, to reduce or eliminate exposure in lieu of warning
  - Requiring contemporaneous record-keeping for investigative cost Plaintiff seeks to recover in settlement.

# CALIFORNIA PROPOSITION 65: ENFORCEMENT (CONTINUED)

## WHY THESE CASES DON'T USUALLY GO TO TRIAL:

- Most of these cases are settled before going to trial.
- Trials are costly, involving attorneys, witnesses, expert witnesses and other “discovery”.
- Preparation, including expert reports and attorneys’ time, can be expensive.
- Winning at trial is often difficult.
- Very hard to get out of a case on Summary Judgment (but can use as a tool to resolve parts of the case)
- Companies don’t want the adverse publicity and stigma that is sometimes associated with trials.

# CALIFORNIA PROPOSITION 65: ENFORCEMENT (CONTINUED)

## ISSUES THAT SHOULD BE CONSIDERED IN SETTLEMENTS:

- Impacts of settlements on other products and product lines;
- Court-approved settlements give “*res judicata*” protection, though it costs a bit more to do it that way;
- How much of the settlement goes to the State, the plaintiff, and plaintiff’s law firm, and timing of payments;
- Covering all chemicals in the product or product line, not just what was in the 60-day notice;

# CALIFORNIA PROPOSITION 65: ENFORCEMENT (CONTINUED)

## ISSUES THAT SHOULD BE CONSIDERED IN SETTLEMENTS:

- Recalls or settlement protections for products already in the distribution pipeline or manufactured prior to settlement date (“sell-through” issues)
- Who is settling? Will manufacturer cover its distribution chain?
- Allowable warnings, chemical concentrations in products, reformulation specifics, and protections.



# CALIFORNIA PROPOSITION 65: WARNINGS

## BACKGROUND:

- Proposition 65 requires “clear and reasonable” warnings when exposures to listed chemicals exceed Safe Harbor Levels.
- Regulations define when and how warnings should take place.
- “Under-warning” is a violation of Proposition 65.
- Nor does the AG want “over-warning” (dilutes real warnings).
- AG wants you to go through a Proposition 65 assessment and determine if a warning is required.
- ***Time-Consideration:*** From the time a chemical is listed, affected parties have one year to determine if their products need warnings.

# CALIFORNIA PROPOSITION 65: WARNINGS (CONTINUED)

## NEW WARNINGS – KEY POINTS:

- August 30, 2016 – California Adopts Amendments to Article 6 “Clear and Reasonable Warnings” of CCR Title 27.
- Still Based on Exposure(s) Exceeding the NSRL or MADL.
- Greater detail on responsible parties, with primary responsibility on “producer” or “packager” of product, to minimize impacts on retailers (see 27CCR §25600.2).
- Must name at least one listed Proposition 65 chemical, if present in product, unlike previous requirements.
- **The new warning regulations become effective August 30, 2018**, but regulated parties have the option of using the new rules now.

# CALIFORNIA PROPOSITION 65: WARNINGS (CONTINUED)

## MATTERS COVERED IN NEW WARNING REGULATIONS:

- Warning placement
- Warning content
- Truncated “short-form” warning statements on products
- Translation
- Written notice

# CALIFORNIA PROPOSITION 65: WARNINGS (CONTINUED)

## WARNING PLACEMENT:

- Specifies labels, shelf signs, and shelf tags at each point of display of the product in “brick and mortar” stores.
- For online and catalog sales, warning must be provided either in full text or a clearly-marked “hyperlink” on the product display page, “or otherwise prominently displaying the warning to the consumer prior to completing the purchase” [see 27 CCR §25602].
- Warning should be likely to be read BEFORE exposure occurs or before product purchase is made.

# CALIFORNIA PROPOSITION 65: WARNINGS (CONTINUED)

## WARNING CONTENT:

- Exclamation point in triangle filled in yellow (if yellow not a color elsewhere on package, black and white is fine).
- The word “WARNING” in bold caps adjacent to triangle.
- Text varies based on endpoints and number of chemicals.

# CALIFORNIA PROPOSITION 65: WARNINGS (CONTINUED)

## WARNING CONTENT (continued):

- Warning language for reproductive toxicant(s):

*“This product can expose you to chemicals including [name one or more chemicals], 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](http://www.P65Warnings.ca.gov).”*

- Warning language for carcinogen(s):

*“This product can expose you to chemicals including [name one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).”*

- For single chemical, omit the words “chemicals including”.

# CALIFORNIA PROPOSITION 65: WARNINGS (CONTINUED)

## WARNING CONTENT (continued):

- Warning language when both a carcinogen and reproduction toxicant both present:

*“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 [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 go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).”*

- As before, if only one chemical named for either endpoint, delete “chemicals including”.

# CALIFORNIA PROPOSITION 65: WARNINGS (CONTINUED)

## “SHORT-FORM” WARNING CONTENT (continued):

- If the product or product packaging is too small for the full warning
- Truncated warning must include:
  - The exclamation point symbol in triangle
  - “WARNING” in Bold Caps
  - “Cancer – [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)”, or
  - “Reproductive Harm – [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)”, or
  - “Cancer and Reproductive Harm – [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)”



# CALIFORNIA PROPOSITION 65: WARNINGS (CONTINUED)

## TRANSLATION:

- Consumer product warning statements must be in the same language(s) used for other product text and warnings, directions, ingredient lists on the label, labeling, or sign accompanying product sale.
- Where the product name is the only thing in a language other than English, this provision does not apply.

# CALIFORNIA PROPOSITION 65: WARNINGS (CONTINUED)

## WRITTEN NOTICE:

- A manufacturer may be compliant with Proposition 65 warning requirements by providing a written notice to the retailer detailing:
  - Exact name and description of product
  - That the product may result in exposures to one or more specific listed chemicals
  - The statement(s) required for warnings or signs at the point of sale
- Written notice needs to be re-issued to retailers every 6 months.

# CALIFORNIA PROPOSITION 65: WARNINGS (CONTINUED)

## SUMMARY REGARDING NEW WARNING REQUIREMENTS:

- New warnings under Proposition 65 are required Aug. 30, 2018; optional phase-in already going on.
- A new warning can take the form of either a warning on the product or written notice to retailers for posted signs.
- New labeling requirements include:
  - Naming at least one specific chemical for each relevant endpoint, or
  - Short form warning, where applicable
- Language (e.g., English, Spanish) must be same language as other product text and other warnings.

# CALIFORNIA PROPOSITION 65: NATURALLY-OCCURRING EXEMPTION

- Proposition 65 allows for exemption from warning requirements only for exposures that are the result of:
  - Human consumption of a food in which the listed chemical is “naturally occurring”; and
  - For consumer products other than food, exposure to a listed chemical that was naturally occurring in food, and “the food” was used in the manufacture, production, or processing of that consumer product [see 27 CCR §25501 (a) and (b)].
- An example is natural fruit sources of fragrance components used in some products, as long as synthetic chemical not added.

# CALIFORNIA PROPOSITION 65: NATURALLY-OCCURRING EXEMPTION (CONTINUED)

- Need to map “farm-to-product” pathway to determine nature of sources and to determine if a naturally-occurring chemical is “boosted” with addition of synthetic version of chemical.
- Exposure assessment only needs to address the portion of a listed chemical that is synthetic in origin, or that exists as background as the result of human activity, or not avoidable by good agricultural or manufacturing practices, for example, the application of herbicides or pesticides, stormwater runoff, or deposition of the chemical from air.
- Exposure assessment does not need to address the portion of a listed chemical that is naturally occurring from a “food” source.

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# CALIFORNIA PROPOSITION 65: NATURALLY-OCCURRING EXEMPTION (CONTINUED)

- If the non-naturally-occurring portion of a food chemical does not result in exposures above the Safe Harbor Level, no warning is required, as well (see 27 CCR §25501(a)(1-4).
- Burden of proof to establish this defense is on the manufacturer or other defendants in the distribution chain.

# CALIFORNIA PROPOSITION 65: NATURALLY-OCCURRING EXEMPTION (CONTINUED)

## EXAMPLES: THE DEVIL IS IN THE DETAILS:

- Example 1: Dried lemon peel is added to an herbal tea mixture
- Example 2: Dried lemon peel is used to make potpourri
- Example 3: Lemon oil derived from lemons is used as a fragrance ingredient for soaps
- Example 4: Synthetic  $\beta$ -myrcene is used as a lemon fragrance for hand soap.
- Example 5: Natural lemon oil containing  $\beta$ -myrcene and synthetic fragrance containing  $\beta$ -myrcene are used to make a hand soap
- Be careful using this exemption and be sure to consult with counsel.

# CALIFORNIA PROPOSITION 65: EXAMPLE CHEMICALS OF INTEREST

- **1,4-Dioxane** – Listed January 1, 1988
- May be present as minor residue in surfactants
  
- **Diethanolamine (DEA)** – Listed June 22, 2012
- Cocamide diethanolamine (CDEA) – Listed June 22, 2012
- Both occurred as foam boosters in soaps and shampoos
  
- **$\beta$ -Myrcene** – Listed March 27, 2015
- May be present in citrus-based fragrances



# CALIFORNIA PROPOSITION 65: KEY TAKE-AWAYS

- Proposition 65 presents a number of challenges for the cleaning products industry.
- Proposition 65 shifts the burden of protecting public health from government to industry for exposures to listed chemicals in excess of allowed risk-based limits.
- Under Proposition 65, a scientifically-defensible exposure/risk assessment is critical for product defense.
- The exposure/risk assessment should focus on the “typical anticipated use,” rather than “worst-case”.

# CALIFORNIA PROPOSITION 65: KEY TAKE-AWAYS (CONTINUED)

- The “deputizing” of “bounty hunters” under Proposition 65 has changed the typical regulatory landscape for enforcement, settlement, and litigation.
- The new warning statement language under Proposition 65 is highly prescriptive and must specify one or more listed chemicals.
- The “naturally-occurring-in-food” exemption may be a suitable remedy for Proposition 65-listed chemicals in some product raw materials derived from food (e.g.,  $\beta$ -myrcene in citrus fragrances).
- **The new warning regulations become effective August 30, 2018**, but regulated parties have the option of using the new rules now.

# Questions and Discussion

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## **GARY WHITMYRE, DABT**

*toXcel*, LLC

[Gary.Whitmyre@toXcel.com](mailto:Gary.Whitmyre@toXcel.com)  
703-754-0248 x8113

7140 Heritage Village Plaza  
Gainesville, Virginia 20155



## **JON BENJAMIN, ESQ.**

Farella Braun + Martel LLP

[Jbenjamin@fbm.com](mailto:Jbenjamin@fbm.com)  
415-954-4971

Russ Building, 235 Montgomery Street  
San Francisco, California 94104

