

# Proposition 65: Key Updates and Hot Topics

---

IFT Food Policy Impact  
February 6, 2018  
Jessica P. O'Connell

**COVINGTON**

BEIJING BRUSSELS DUBAI JOHANNESBURG LONDON LOS ANGELES NEW YORK  
SAN FRANCISCO SEOUL SHANGHAI SILICON VALLEY WASHINGTON

[www.cov.com](http://www.cov.com)

# Agenda

---

- Overview of general requirements
- 2018 updates to regulations
- Recently listed substances
- Questions

# Proposition 65: General Requirements

---

## Prop 65 Overview: Background

---

- Enacted by CA voters in 1986
- Fundamentally a *warning* requirement - penalties can be assessed against a business that knowingly exposes consumers, *without warning*, to chemicals that CA has identified as causing cancer or reproductive harm
- Warnings must be “clear and reasonable”
- Only applies to businesses with 10+ employees

## Prop 65 Overview: Enforcement

---

- California AG's office or other state/local prosecutors
- Individuals acting in the “public interest”
- Penalties: up to \$2,500, per violation, per day
  - *and* reasonable attorney's fees
  - possibility of injunctive relief instead
- Preemption arguments or other constitutional defenses generally not successful (but *see* nicotine)

# Prop 65 Overview: Requirements

---

- Business must warn a person before “*knowingly and intentionally*” exposing that person to a listed chemical
- Business must be aware that it is causing an exposure (but no requirement that business be aware of Prop 65 obligations)
- Exposure must result from a deliberate act, like the sale of a product
- Warning must be “*clear and reasonable*”:
  - clearly communicate that the chemical is known to cause cancer, and/or birth defects or other reproductive harm;
  - effectively reach the person before exposure
- Exposure? Consumer product; environmental; occupational



# Prop 65 Overview: Key Exemptions

---

- Exposures that pose no “significant risk” of cancer: exposure is calculated to result in not more than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime
  - CA has identified **No Significant Risk Levels (NSRLs)** for certain listed substances known to cause cancer
- Exposures that produce no observable reproductive effect at 1,000 times the level in question
  - CA has identified **Maximum Allowable Dose Levels (MADLs)** for substances known to cause reproductive toxicity

\*Current list of “safe harbor” levels:

<https://oehha.ca.gov/proposition-65/general-info/current-proposition-65-no-significant-risk-levels-nsrls-maximum>

\*Company can establish NSRL or MADL on its own

## Prop 65 Overview: Key Exemptions

---

- Exposure to substances that are “naturally occurring” in foods
  - meaningfully litigated in the past
  - “natural background”
  - chemical is not added as a result of any human activity (pollution?)
  - GMPs could not prevent the chemical from being part of the product
- Governmental agencies
- Discharge will not cause a “significant amount” (i.e., any detectable amount) of the listed chemical to enter any drinking water source



## Prop 65 Overview: Process

---

- OEHHA maintains list of substances known to cause cancer or reproductive toxicity – updated at least once a year
  - chemicals identified by the WHO’s International Agency for Research on Cancer (IARC) as causing cancer in humans or laboratory animals
  - two expert committees: Carcinogen Identification Committee (CIC) and the Developmental and Reproductive Toxicant Identification Committee (DARTIC)
  - authoritative bodies: EPA, FDA, NIOSH, NTP, IARC
  - required by federal government (e.g., Rx drugs)
- Listing: public notice, comment period, review, final decision
- Substances can be “delisted” too



# Prop 65 Overview: Process

---

- Current list: <https://oehha.ca.gov/proposition-65/proposition-65-list>

STATE OF CALIFORNIA  
 ENVIRONMENTAL PROTECTION AGENCY  
 OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT  
 SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY  
 December 29, 2017

Chlorotrianisene	cancer	569-57-3	September 1, 1996
Chlorozotocin	cancer	54749-90-5	January 1, 1992
Chlorpyrifos	developmental	2921-88-2	December 15, 2017
<del>Chlorsulfuron</del>	<del>developmental, female,</del>	<del>64902-72-3</del>	<del>May 14, 1999</del>
<u>Delisted June 6, 2014</u>	<u>male</u>		
Chromium (hexavalent compounds)	cancer	---	February 27, 1987

## Prop 65 Overview: Process

---

- Can be enforced by AGs, state/district attorneys, or private enforcers – most action by private enforcers
- Private enforcers must serve “60-day notice” to alleged violator and AG’s office, should identify basis for potential action
  - Notices are posted on AG’s website:  
<https://oag.ca.gov/prop65/60-day-notice-search>
- Alleged violator can respond with potential defenses
- Once 60 days has passed, private enforcer can initiate litigation if public prosecutors have not
- Potential defenses:
  - Meets requirements for exemption (testing/exposure assessment)
  - Provided adequate warning
  - Statute of limitations

## Prop 65 Overview: Stats

---

- 2016: 760 settlements, \$30.2 million settlement payments, incl. \$21.5 million attorney's fees
- 2015: 582 settlements, \$26.2 million settlement payments, incl. \$17.8 million attorney's fees
- 2014: 663 settlements, \$29.5 million settlement payments, incl. \$21 million attorney's fees
- 2013: 352 settlements, \$17.4 million settlement payments, incl. \$12.7 million attorney's fees
- 2012: 437 settlements, \$22.6 million settlement payments, incl. \$15.6 million attorney's fees

\*source: annual AG reports (<https://oag.ca.gov/prop65/annual-settlement-reports>)

# Proposition 65: Key Updates

---

## New “Safe Harbor” Warnings

---

- Prop 65 requires “clear and reasonable” warnings; “safe harbor” warning is presumed “clear and reasonable”
- Operative on Aug. 30, 2018
  - Until then can use existing or new
  - Does not apply to parties subject to court settlements/final judgments
  - Compliance date applies to when a product is “made”


# New “Safe Harbor” Warnings

---

- Key Changes:
  - Warning should identify, *by name*, at least one listed chemical in the product for each endpoint for which the warning is provided
  - Warning should include link to CA website
  - Online retailers must provide a Prop 65 warning for the product on the retailer's website in addition to the warning that accompanies the actual product
    - Product display page
    - Clear hyperlink
    - Otherwise prominently display: warning is not “prominently displayed” if the purchaser must search for it in the general content of the website
  - Non-English warnings required in certain circumstances

# New “Safe Harbor” Warnings

---

- Comparison old/new content for most consumer products
  - OLD -  
WARNING: This product contains a chemical known to the State of California to cause cancer.
  
  - NEW -  
 **WARNING:** This product can expose you to chemicals including arsenic, which is known to the State of California to cause cancer.  
For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).
  
  - SHORT -  
 **WARNING:** Cancer – [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)



## New “Safe Harbor” Warnings

---

- Food has its own “tailored” warning (no need to include pictogram but should be enclosed in a box):

**WARNING:** Consuming 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/food](http://www.P65Warnings.ca.gov/food).

- Truncated on-product “tailored” safe harbor warning for food:

**WARNING:** Cancer - [www.P65Warnings.ca.gov/food](http://www.P65Warnings.ca.gov/food).

## Key New Listings

---

- Acrylamide (warning required Feb. 25, 2012)
  - result of thermal processing (Maillard reaction)
  - 0.2 micrograms/day safe harbor level
- Furfuryl alcohol (warning required Sep. 30, 2017)
  - result of thermal processing (Maillard reaction)
  - no regulatory safe harbor level
- Glyphosate (warning required July 7, 2018)
  - no regulatory safe harbor level
- BPA (warning required May 11, 2016)
  - emergency regulation in 2016 to allow point of sale warning at retailers; point of sale allowance expired December 2017
  - 3 micrograms/day safe harbor (dermal exposure from solid materials); no safe harbor for oral exposure

# Questions?

---

Jessica P. O'Connell  
[jpoconnell@cov.com](mailto:jpoconnell@cov.com)

**COVINGTON**

BEIJING BRUSSELS DUBAI JOHANNESBURG LONDON LOS ANGELES NEW YORK  
SAN FRANCISCO SEOUL SHANGHAI SILICON VALLEY WASHINGTON

[www.cov.com](http://www.cov.com)