



2017

THE ALMOND CONFERENCE

PROPOSITION 65: WHEN IS A WARNING REQUIRED?

Room 306-307 | December 7 2017



AGENDA

- **Emily Rooney**, Agriculture Council of California, moderator
- **F. Jay Murray**, Murray & Associates





Agricultural Council
of California

Protecting California's #1 Industry

ALMOND CONFERENCE

December 7, 2017

Protecting California's #1 Industry

Legislative Attempts to Label Food

2016:

- AB 2725: Would have required any food product with a quality date to utilize the language, “best if used by”

2015:

- ABX2-14: Would have required labeling of food that is irrigated with water from the oil extraction process

2014:

- SB 1381: GMO labeling bill defeated in State Senate
- GMO initiative on ballot

California's Proposition 65

- Passed as a voter initiative in 1986
- Proposition 65 requires the state to maintain and update a list of chemicals known to the state to cause cancer or reproductive toxicity
- Over 900 chemicals on list
- Many naturally occurring in food products or used for food safety purposes

The Cost of Doing Business

2016 Settlement Amounts

- \$30,150,111 million in settlements in 2016
- \$21,561,113 in attorney's fees and costs

2015 Settlement Amounts

- \$26,226,761 million in settlements in 2015
- \$17,828,941 in attorney's fees and costs



Prop. 65: New Warning Regulations

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.

- New warning in effect
- Old warning still good until August 30, 2018

Prop. 65: Bisphenol-A

- OEHHA listed BPA in May 2015
- Store signage program active
- OEHHA created BPA website listing products
- Website contains names, descriptions, container sizes, and UPCs
 - “Used by” date indicates when BPA was *last used* in the packaging
- **This program expires on December 30, 2017**
- List available at: <https://www.p65warnings.ca.gov/bpalist>

WARNING

Many food and beverage cans have linings containing bisphenol A (BPA), a chemical known to the State of California to cause harm to the female reproductive system. Jar lids and bottle caps may also contain BPA. You can be exposed to BPA when you consume foods or beverages packaged in these containers.

For more information go to:

www.P65Warnings.ca.gov/BPA



Prop. 65

- Glyphosate
- BPA
- Arsenic
- Acrylamide
- Lead
- Furfuryl Alcohol
- Chlorpyrifos
- Vinylidene Chloride

Proposition 65: When Is a Warning Required?

F. Jay Murray, Ph.D.
Murray & Associates





Topics

- Prop 65 Basics
- 60-Day Notices
- New Warning Requirements
- Substances of Interest
 - Propylene Oxide, Acrylamide, Glyphosate, Lead, Chlorpyrifos

Safe Drinking Water and Toxic Enforcement Act of 1986





Overview of Proposition 65

- Drafted by lawyers and appeared as Prop 65 on the November 1986 ballot
- Passed by voter initiative with a 2:1 margin
- This right-to-know law is concerned only with two types of substances:
 - Carcinogens
 - Developmental and Reproductive Toxicants



What Does Proposition 65 Prohibit?

- Exposing people in California to listed chemicals without a prior warning.
- Discharging listed chemicals into “sources of drinking water” in California
- Today, there are over 900 chemicals on the Proposition 65 list



To Whom Does Prop 65 Apply?

- Companies doing business in California
 - If a product is sold in California, then it must comply with Proposition 65
- The only exemptions are:
 - Companies with fewer than 10 employees
 - Governmental units
 - Anyone operating a public water system

Prop 65 Enforcement

- Government is not the primary enforcer
- Private citizen (“bounty hunter”) notices/lawsuits, (plaintiffs can receive 25% of penalties plus legal fees)
- Purpose of the “60-Day Notice”
- Plaintiff need only show an exposure
- Burden of proof shifts to defendant



What should I do if I get a 60-day notice?

- Don't throw it away
- Find a good Prop 65 attorney
- Develop defense strategy
- Talk plaintiffs out of it (long shot)
- Settle with plaintiffs
- Go to court

Warnings will change in 2018

- Current warning

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

- After August 30, 2018

“WARNING: Consuming this product can expose you to chemicals including [name listed chemical], which is known to the State of California to cause cancer [or birth defects or other reproductive harm]. For more information go to P65Warnings.ca.gov/food.”



Exceptions to Warning Requirement

- Less than 12 months after listing
- Exposure at levels that present “no significant risk” of cancer
- Exposure at levels less than 1/1000 of the no observable effect level for DARTS
- Federal law governs warning in a manner that preempts state authority
- Naturally occurring exemption

NSRLs and MADLs

- NSRL = No Significant Risk Level
 - Theoretical 1 in 100,000 cancer risk
- MADL = Maximum Allowable Dose Level
 - 1/1000 of the no effect level in most sensitive animal or human study
- Safe Harbor can be set by OEHHA
- Most listed chemicals have no safe harbor



Impact of Prop 65 on Almonds

- Foods products have been under siege for the past decade (snack foods, French fries, fruit juices, coffee, grilled chicken)
- In the past 6 months, there have been a dozen 60-day notices targeting products containing almonds (cookies, bars)
- In the last month, there have been two 60-day notices targeting roasted and dry roasted almonds

How is exposure determined?

- Exposure = C x S X F
 - Where C = concentration
 - S = serving size
 - F = frequency of consumption
- For foods, exposure means the average exposure for the average consumer of the food



Propylene Oxide (PPO)

- PPO was listed as a carcinogen in 1988
- No safe harbor level has been established
- NSRL estimated as 280 mcg/day based on EPA cancer risk assessment
- Estimated average almond consumption of 1.8 lb/yr (2.25 g/day)
- Assumes that 100% of the U.S. general population eats almonds



Hypothetical Estimate of Exposure to PPO from Almonds

- PPO residues on almonds vary depending on multiple factors
- Assumed the average concentration of PPO on almonds after 42 days is 1.9 ppm
- Assume average consumption of 1.8 lb/yr (or 2.25 g/day)
- Average exposure to PPO is calculated to be 4.3 mcg/day (less than 280 mcg/day)



Acrylamide (AA) and Prop. 65

- Discovered in foods in 2002
- Formed from heating asparagine and reducing sugars
- Listed as carcinogen in 1990 and a reproductive toxicant in 2011
- NSRL = 0.2 mcg/day; MADL = 140 mcg/day
- Alternative NSRL: 1.2-1.4 mcg/day based on recent risk assessments by ATSDR and EFSA

PROPOSITION 65 WARNING

Chemicals known to the State of California to cause cancer and reproductive toxicity, including acrylamide, are present in coffee, baked goods, and other foods or beverages sold here. Acrylamide is not added to our products, but results from cooking, such as when coffee beans are roasted or baked goods are baked. As a result, acrylamide is present in our brewed coffee, including coffee made at home or elsewhere from our beans, ground or instant coffee, baked goods or other foods sold here, in grocery stores or other retail locations.

Your personal cancer risk is affected by a wide variety of factors. The FDA has not advised people to stop drinking coffee or eating baked goods that contain acrylamide. For more information regarding FDA's views, see www.fda.gov. For more information about acrylamide and Proposition 65, visit www.oehha.ca.gov/prop65/acrylamide.html.





Glyphosate

- Active ingredient in Roundup herbicide
- Listed as a Prop 65 carcinogen in July 2017 based on IARC classification
 - IARC reviewed only 4 of 14 cancer studies
 - Human study showing no link was withheld
 - IARC Working Group scientist claimed no conflict of interest but was paid \$160K by glyphosate plaintiff's attorneys



Glyphosate NSRL

- OEHHA proposed a draft NSRL of 1 100 micrograms/day
- Glyphosate residues on almonds should be well below the proposed NSRL
- Enforcement will begin in July 2018
- Burden of proof on growers and producers to show exposures are below the NSRL



Lead

- Lead is ubiquitous
- Current MADL for lead is 0.5 mcg/day
- It is difficult for food products to meet the current MADL
- CEH filed a petition requesting OEHHA to reduce or rescind the current safe harbor
- Basis for the current safe harbor level is the OSHA PEL document (1978)



Lead Regulations May Change

- OEHHA is expected to propose changes in the lead regulations
- Fruit juice and baby food litigation (ELF vs. Beechnut)
- In 2015, OEHHA proposed lowering the MADL from 0.5 to 0.2 mcg/day
- Impact on future litigation



Breaking News: Chlorpyrifos

- Chlorpyrifos is an organophosphate pesticide
- 25% of all pesticides used in CA
- Will be added to the Prop. 65 list as a developmental toxicant in December 2017
- Warning requirement triggered 1 year after the date of listing



Conclusions

- Prop 65 has the potential to impact your business
- Many chemicals of potential interest are on the front burner
- It is critical to monitor new developments
- The Almond Board of California continues to stay on top of Prop 65

Thank you!



What's Next

Thursday, December 7 at 6:00 p.m.

Doors open at 5:30 p.m.

- **Gala Dinner**, sponsored by Farm Credit Alliance
- Entertainment:
 - Magic and Comedy with Adam Trent
 - Dancing with Apple Z



FARM CREDIT

American AgCredit | Farm Credit West
CoBank | Fresno Madera Farm Credit
Golden State Farm Credit