



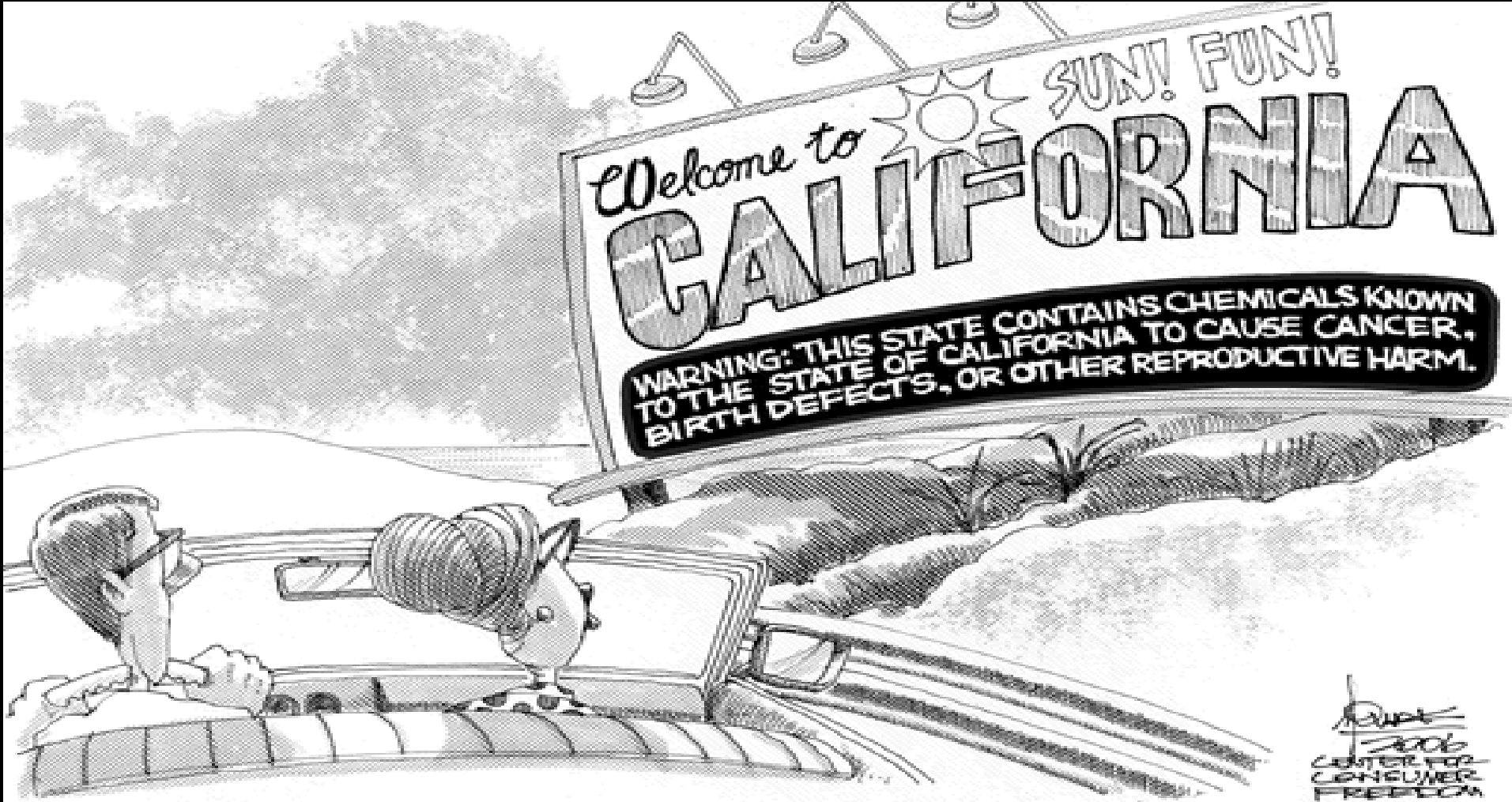
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Intro to Proposition 65

What Ice Cream Companies Need to Know

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April 10, 2018



Agenda

1. Proposition 65
2. Furfuryl alcohol
3. IDFA activities
4. Questions and answers



California's Proposition 65

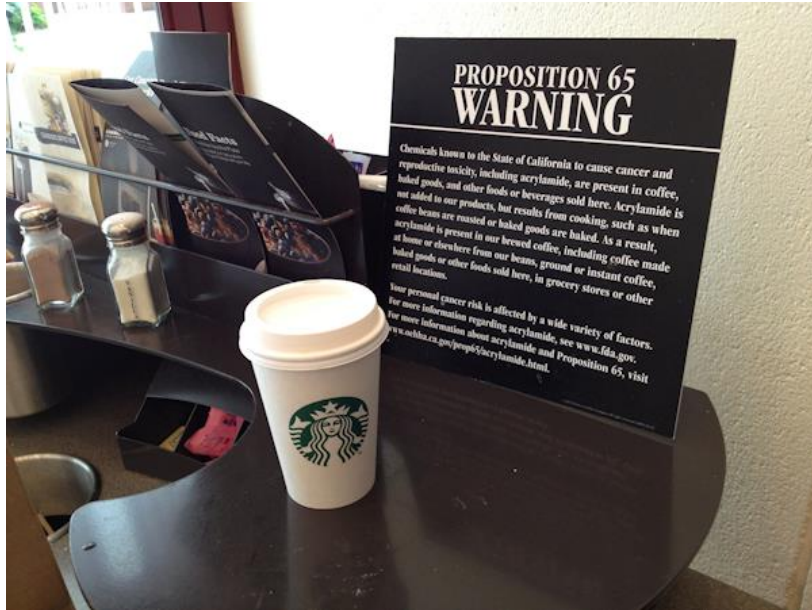
- State law adopted in 1986
- Requires the state to revise and republish at least once per year the list of chemicals known to the State to cause cancer or reproductive toxicity
- Over 900 chemicals listed
- Consumer right-to-know: requires a warning/notice in instances when a product contains a listed chemical (even if health experts conclude there is low likelihood of actual health risk)

California's Proposition 65

- Proposition 65 is a “right to know” law -- not a safety statute
- Office of Environmental Health Hazard Assessment (OEHHA)
- Proposition 65 involves conditions under which California residents must be warned
 - Retail sales
 - Internet sales



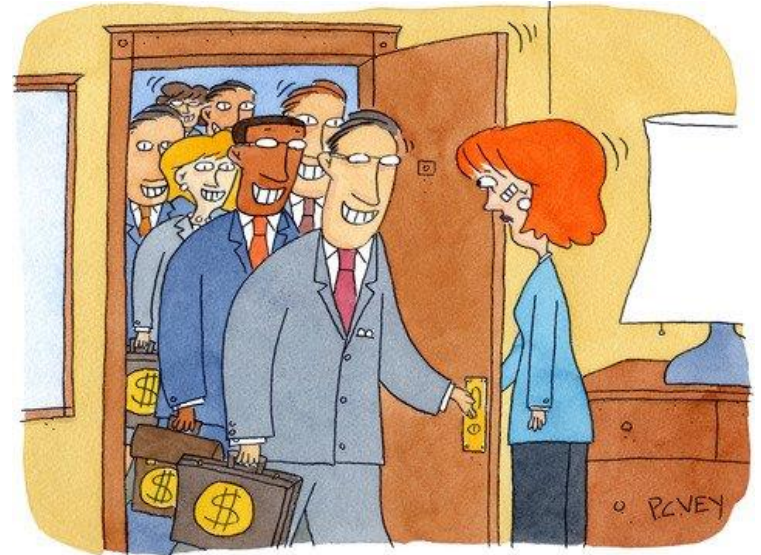
Proposition 65 Warning for Foods



WARNING: Consuming this product can expose you to chemicals including acrylamide, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov/food.

Enforcement

- State can sue to enforce warning requirements
- Bounty hunter provision allows private parties to bring a law suit (and collect substantial sums of money)
- Violations of Proposition 65 are subject to civil penalties of up to \$2,500 per day per violation; 25% of any assessed penalty goes to a successful plaintiff
- Lawsuits usually result in consent decree settlements



Consent Decree Settlements

- Civil penalties and attorneys fees
- Target listed chemical levels
- Specified warning language
- Agreement between plaintiffs or the state and individual companies
- Many contain “opt-in” provisions
- Require annual monitoring to document compliance

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MEMO ENDORSED
as modified (pp11+12)

~~PROPOSED~~ STIPULATED
FINAL JUDGMENT AND
CONSENT DECREE

Civ. No. 08 Civ. 2977

USDC SDNY
DOCUMENT
ELECTRONICALLY FILED
DOC #:
DATE FILED: 3/25/08

JUDGMENT AND CONSENT DECREE

Judgment and Consent Decree is based on an
New York, Illinois, and Michigan (the “Plaintiff
violation and other antitrust violations by Herman
Miller for the Home division (“HMM”) which

Defense - Naturally Occurring Exemption

- Prop 65 Excludes Naturally Occurring Substances:
 - Must be naturally present in the environment with no intervention by man (including processing)...company bears burden of proof
 - If listed substance can form naturally in the food, the processor shall at all times utilize quality control measures that reduce the substance “to the lowest level currently feasible”
- 27 CCR § 25501



Safe Harbor Exemption

- Warning is not required if within a safe harbor:
 - OEHHA publishes many safe harbors (but not yet for furfuryl alcohol)
 - Company (with help of expert toxicologist) can calculate safe harbor but bears risk OEHHA would disagree
- Safe harbor is reported in micrograms consumed/day



Defense - Safe Harbor Exemption

- Safe harbors can be established by OEHHA or industry
- For carcinogens, the risk level which represents no significant risk is less than a 1 in 100,000 increase in risk of cancer over 70 years, **except** where sound considerations of public health support an alternative level, as, for example:
 - “*where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination*”
- 27 CCR 25703(b)(1)



Keep Your Eye on Coffee

- Coffee industry being sued for failing to warn of acrylamide
- Industry is arguing that acrylamide forms due to heating steps needed for food safety so 1:100,000 does not apply
- Proposed ruling against the coffee industry
- Stay tuned



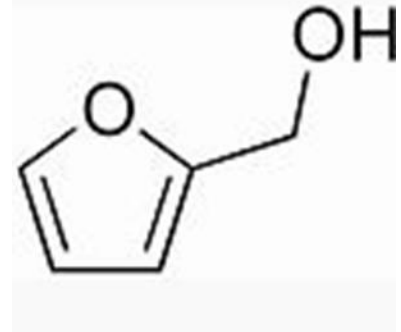
2. Furfuryl Alcohol: Current Case Study

- OEHHA listed furfuryl alcohol under Proposition 65 on September 30, 2016, as a chemical known to the state to cause cancer for purposes of Proposition 65
- Sometimes intentionally added to foods as a flavoring
- Formed during heat processing – Maillard reaction



Furfuryl Alcohol

- The compliance date for Proposition 65 warning regarding furfuryl alcohol – containing products was **September 30, 2017**
- OEHHA has not established a safe harbor for furfuryl alcohol
- We know of one conservative furfuryl alcohol “safe harbor” (cancer).
- An alternative risk level for furfuryl alcohol in foods (i.e., higher) may also be developed.



Recent Activity

- Bounty hunters must file 60-day notice with state AG before initiating suit
- A total of six 60-day notices have been filed since the compliance date
 - Targeting primarily food retailers and manufacturers of potato based snacks and pretzels
 - Center for Environmental Health (CEH) has filed four of the six



Other Notable Listed Chemicals

- Lead (cocoa)
- Cadmium (cocoa)
- Acrylamide (baked inclusions like cookies and coffee)
- 4-MEI (caramel coloring and baked inclusions like cookies)
- Mercury (60-day notices from early 2000s on chocolate milk and yogurt)
- Propylene Oxide (flavoring)
- Ethylene Oxide (flavoring)

Intake Assessments

- Industry won a major victory when calculating exposures under Prop 65
- Geometric mean for intake
- Adjusted for food frequency
- Use average values for production lots



New California Regulation on Warnings

- In practice, for a food product that may expose consumers to both listed carcinogens and reproductive toxicants, the following warning content is deemed compliant by OEHHA:
- ***“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 [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/food.”***
- When the warning is provided on the food product label, it must be set off from other surrounding information, enclosed in a box and comply with the content requirements

3. IDFA Activities

- Identified lab capable of conducting validated testing of furfuryl alcohol in dairy products
- Collected a spectrum of dairy product samples for testing
- Confidential results shared with IDFA members
- Provided preliminary assessment on Prop 65 compliance
 - Note the preliminary assessment was based on certain assumptions that may not be true for all member companies
 - Each company should consult their own legal counsel to determine warning obligation

IDFA Activities – Next Steps

- Conduct testing to determine at which manufacturing steps the furfuryl alcohol forms
- Evaluate results and potential mitigation strategies
- Consider developing alternative safe harbor
- Determine engagement and advocacy

What To Do If You Receive a Demand Letter?



- Bounty hunters are required to give companies notice of alleged violation
- Collect the facts
 - Do your products have furfuryl alcohol?
 - What levels?
- Work with legal counsel to develop best possible strategy
 - How do your numbers compare with safe harbor, if one exists?
 - Is it worthwhile to support the development of an alternative risk level?

New Ingredient Specification Sheet with Prop 65 Listed Chemical?



- Naturally-occurring exemption defense has a very high bar
- Safe harbor exemption based on the use level?
- Should I test the listed chemical in the finished product that is subjected to further processing (e.g., furfuryl alcohol is volatile and might evaporate during heating)

Conclusions

- Prop 65 is novel law
- Becoming more prevalent in the food industry
- Every company selling product in California needs to be aware
- Furfuryl Alcohol is current example
- IDFA is on the case!



Questions?



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