



NewsFeed™
Foley's Quarterly Food Industry Web Conference Series

Presenters:

Vicki Hicks, Government & Public Affairs

Richard Casper, Commercial Transactions & Business Counseling

Elizabeth Cason, Environmental Regulation

S. Wayne Rosenbaum, Environmental Regulation

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Today's Presenters



Vicki Hicks
Washington, D.C.



Richard Casper
Milwaukee



Elizabeth Cason
San Diego



Wayne Rosenbaum
San Diego

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Housekeeping

- We will take questions throughout the program via the Q & A tab at the top of your screen located in the tool bar and live questions at the end of the program
- Foley will apply for CLE credit after the Web conference. If you did not supply your CLE information upon registration, please e-mail it to mlopez@foley.com
- Today's program is being recorded and will be available on our Web site
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2008 Farm Bill: Prospects for Passage

2008 Farm Bill: Prospects for Passage

- Current farm bill expires on March 15th. What happens if Congress does not pass the 2008 farm bill by that date?
- Conference committee deliberations: What to expect between now and final passage of the farm bill
- Walking the tightrope: With a strong veto threat from the White House, how will Congress pass a farm bill that satisfies its constituents while also avoiding a veto?
- Country of Origin Labeling: What changes has Congress made to current law, and when will those changes go into effect?

Common Mistakes in Procurement Contracts

Unknown Counterparty

A correct legal name is the foundation for all of your rights and responsibilities, and for your “due diligence” regarding the party with which you are working. (“Smith Foods”?)

Failure to Allocate Clearly Rights/Responsibilities for Labeling

- whose trademarks/trade names?
- artwork
- legal disclosures (including ingredients)
- product claims
- instructions

Assuming Exclusivity

Exclusivity, including a commitment to purchase requirements, must be express, clear and “reasonable.”

Simple *Force Majeure* Clause

- What must the affected party do during the *force majeure* (particularly in the context of shortages)?
- What may the unaffected party do during the *force majeure*?
- How long must the unaffected party wait before moving on?

Vagueness

Imprecise pricing, term and/or volume may render a “contract” unenforceable or terminable at will by either party.

“Kitchen-Sink” Confidentiality

Proposition 65 and the Food Industry

Introduction

- What is Proposition 65
- What does Proposition 65 require
- Who can enforce Proposition 65
- Recent Trends in the Food Industry
- Conclusions

What Is Proposition 65?

- In November 1986, California voters approved Proposition 65
 - An initiative to address growing concerns about exposures to toxic chemicals
- That initiative became *The Safe Drinking Water and Toxic Enforcement Act of 1986*

What Does Proposition 65 Require?

- Identify the presence of Prop 65 Chemicals
- Control the use of Prop 65 Chemicals
- Warn of the presence of Prop 65 Chemicals

Identification

- Proposition 65 requires the Governor to publish a list of chemicals that are known to the State of California to cause cancer, birth defects or other reproductive harm
- This list must be updated at least once a year
- There are over 800 chemicals on the list and growing

What kinds of chemicals are on the list?

- The list contains a wide range of chemicals, including dyes, solvents, pesticides, drugs, food additives, and by-products of certain processes
 - These chemicals may be naturally occurring, or synthetic
 - Note Naturally occurring exemption for food products
 - Many of them are ingredients of common food and drink products
 - French Fries (Acrylamides)
 - Hamburgers (PAHs)
 - Soft Drinks (Caffeine)
 - Tuna Fish (Mercury)
 - Plastic liners in food packaging (DIDP)

How Does a Chemical Get Listed?

- The State of California relies upon information that already exists in the scientific literature when determining the threat of a chemical
- A chemical is listed if the “state's qualified experts” -- two independent committees of scientists and health professionals appointed by the Governor -- find that the chemical has been clearly shown to cause cancer or birth defects or other reproductive harm
- A chemical can be listed if it has been classified as a carcinogen or as a reproductive toxin by an organization that has been designated as “authoritative” for purposes of Proposition 65
- A chemical can also be listed if it is required to be labeled or identified as a carcinogen or as a reproductive toxin by an agency of the state or federal government.

Control

- Proposition 65 imposes certain controls that apply to chemicals that appear on this list
- These controls are designed to
 - protect California's drinking water sources from contamination by these chemicals,
 - allow California consumers to make informed choices about the products they purchase, and
 - enable residents or workers to take whatever action they deem appropriate to protect themselves from exposures to these chemicals

What Are the Responsibilities of Companies Doing Business in California?

- Any company with ten or more employees that operates within the State or sells products in California must comply with the requirements of Proposition 65 (includes internet sales)
- Under Proposition 65, businesses are:
 - Prohibited from knowingly discharging listed chemicals into sources of drinking water; and
 - Required to provide a “clear and reasonable” warning before knowingly and intentionally exposing anyone to a listed chemical
 - This warning can be given by a variety of means
 - labeling a consumer product
 - placing warnings in the user’s manual
 - posting signs at the workplace
 - publishing notices in a newspaper

When Must a Warning be Given?

- The business issuing the warning knows that one or more listed chemicals is present in
 - its product
 - its workplace
 - or its emissions into the environment
- Knowledge of the presence of the product is sufficient to meet the “knows” standard

When Must a Warning be Given? (cont'd)

- Under the law, a warning must be given unless a business demonstrates that the exposure it causes poses no significant risk
 - For a chemical that is listed as a carcinogen, the “no significant risk” level is defined as the level which is calculated to result in not more than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime
 - For chemicals that are on the list as reproductive toxicants, the no significant risk level is defined as the level of exposure which, even if multiplied by 1,000, will not produce birth defects or other reproductive harm

What Does a Warning Mean?

- When a warning is given by a business, it means one of two things:
 - the business has evaluated the exposure and has concluded that it exceeds the “no significant risk” level; or
 - The business has chosen to provide a warning simply based on its knowledge about the presence of a listed chemical, without attempting to evaluate the exposure
 - In these cases, actual exposure could be below the Proposition 65 level of concern, or could even be zero

Compliance with California's Prop 65 Warning Requirements

- Manufacturers, Distributors and Retailers Beware!
 - Businesses have paid millions of dollars in settlements for alleged violations of California's Proposition 65 warning requirements
 - Thousands of businesses have received a formal "notice of intent to sue" under Prop 65 from lawyers representing private parties, environmental organizations and labor unions alleging failure to provide the requisite warning prior to exposing individuals to substances known to cause cancer or birth defects
 - Plaintiffs have obtained judgments against and extracted settlements from:
 - manufacturers and distributors of products such as french fries, chocolate, hamburgers, breakfast cereals fresh fish tuna fish, glassware, food and beverage containers, water filters (pending).
 - hotel and restaurant chains for exposure to second-hand tobacco smoke and candles

Prop 65 lawsuits have little or nothing to do with "Safe Drinking Water" or "Toxic Enforcement"

- A product that contains a relatively minute, but detectable level of a "listed" substance may trigger the duty to warn under Prop 65, making thousands of products subject to the warning requirements
- The penalty for failure to warn is a fine of up to \$2,500 per day per violation, which can easily skyrocket into the millions
 - Each sale or exposure is considered a separate violation
 - Typically, plaintiffs extract smaller settlement amounts from businesses

Prop 65 applies to companies with 10 or more employees doing business in California, including out-of-state manufacturers that place products into California commerce

- California represents one of the world's largest economies
 - many businesses have product sales in California, even if distributed to the state by some third party
- Both the manufacturer and distributor, as well as a retailer, if any, are subject to Prop 65 requirements
 - it is often the manufacturer that is most easily identified and targeted by Prop 65 plaintiffs
 - citizen plaintiffs will also name retailers as a way of pressuring manufactures into settlement

Prop 65 prohibits a business from knowingly and intentionally exposing any person in the State to a "listed" substance without first giving a "clear and reasonable" warning

- Prop 65 does not actually prohibit any harmful exposure
- It does not regulate the materials used to manufacture a product
- It prohibits an exposure to a substance without first providing a "warning" that the product contains a substance that is known to the state to cause (1) cancer or (2) reproductive harm
 - Plaintiff "bounty hunters" are not required to present evidence of actual harmful exposures – only the presence of the listed chemical

It can be expensive and difficult for most businesses to take advantage of exposure-related exemptions

- A business is exempt from the warning requirement if the exposure levels are below safe harbor levels established by OEHHA or if it obtains a “safe use determination” from the State
- To obtain a safe use determination (SUD), a business must utilize a California Office of Environmental Health Hazard Assessment (OEHHA) approved laboratory to
 - identify the level of exposure posed by the product or business activity, and
 - determine whether the exposure exceeds the relevant criteria assuming all exposure pathways for the duration of the exposure.
 - only three SUD’s have ever been granted

If a business has not previously obtained a safe use determination, a “clear and reasonable” warning is required for three types of exposures:

- Consumer product exposures
- Environmental exposures
- Workplace/occupational exposures

Prop. 65 requires that the warning must be “reasonably calculated” to make the warning message available prior to exposure

- There is limited judicial interpretation of what constitutes a clear and reasonable warning other than the regulatory Safe Harbor Warning. A safe harbor warning *message* is conclusively deemed to be reasonably calculated:
 - WARNING: This product contains chemicals known to the State of California to cause cancer or birth defects or other reproductive harm
- In most cases, a warning displayed on the actual product or its immediate container is a “reasonably calculated” warning *method*
- Businesses should consult California counsel who can provide information concerning industry practices and duty of care

Consumer Product Exposure Warnings

- A consumer product exposure “results from a person’s acquisition, purchase, storage, consumption, or the reasonably foreseeable use of a consumer good, or any exposure that results from receiving a consumer service”

There are Few Exemptions From Prop 65 Requirements

- Courts have generally limited the federal preemption of Prop 65 to the federal Occupational Safety and Health Act as it applies to work place exposures and FIFRA as it applies to insecticides, FDA as it applies to prescription drugs
 - But note that companies are currently seeking broader preemption opinions from FDA concerning food products
- Businesses should not rely on an exemption without a thorough, specific opinion from an attorney experienced in Prop 65 compliance

Food Industry Issues

- Caffeine
 - Currently being considered for listing
 - Exemption for “naturally occurring” caffeine: what will that entail?
 - Will impact soft drink and energy drink manufacturers, others as well
 - Safe harbor level well below caffeine in even one can of coke

Food Industry Issues (cont'd)

- Acrylamide
 - Created when starchy foods are baked, roasted, fried or toasted at high temperatures
 - Wide range of defendants in ongoing cases, including Frito-Lay, P&G, Costco, Burger King, McDonalds, KFC and HJ Heinz
 - Cases brought by both the State Attorney General and private plaintiffs

- PAH
 - Found in smoked or barbequed meat or fish
 - Cases brought by private plaintiffs against Burger King, Carl's Jr. and Hardee's

Food Industry Issues (cont'd)

- Tuna and Beef
 - Mercury in tuna, dioxins and PCBs in beef and liver products

 - Attorney General and private plaintiffs brought suit against the three largest canned tuna suppliers; private plaintiffs threaten suit against beef retailers and manufacturers

 - Court determined warning labels not warranted based in part on letter from FDA stating that Prop 65 is in direct conflict with FDA policy on tuna; meat industry sought declaratory judgment that Prop 65 is preempted by federal meat inspection laws

Current Trends

- Food retailers are seeking indemnity from manufacturers for Prop 65 claims
 - Retailers are concerned about liability
 - Product defect doctrines not applicable
 - Retailers have significant market power
- Manufacturers have begun proactive testing programs, and are considering offering limited Prop 65 indemnities based on testing and to control future litigation

Recent Attack on Prop 65 for the Food Industry

- Swanson Health Products Inc. asked FDA to exempt all food and dietary supplements from Prop 65 based on conflict between the two regulatory schemes and federal preemption doctrine
 - Based on acrylamide: FDA policy statement from 2003 urging Prop 65 warnings be put on hold under a federal risk assessment completed
 - Preemption arguments usually made on a case-by-case basis

Conclusions

- Proposition 65 is a warning statute
 - The warnings extend to over 800 compounds
 - These compounds are ubiquitous in commerce
- Failure to provide adequate warnings leaves manufacturers, distributors and retailers open to significant liability
- Proposition 65 is enforceable by citizen suit
 - over \$170,000,000 have changed hands in the last ten years
- Clients should be alerted to their potential liability and take appropriate action if
 - They manufacture a product that ends up in California
 - Distribute a product to California
 - Sell a product in California

Questions & Answers

Contact Us

Vicki Hicks

Of Counsel

3000 K St., NW, Suite 500

Washington, D.C., 20007

Tel: 202.295.4073

vjhicks@foley.com

Elizabeth Cason

Associate

402 W. Broadway, Ste 2100

San Diego, CA 92101

Tel: 619.685.4634

ecason@foley.com

Richard Casper

Partner

777 E. Wisconsin Ave.

Milwaukee, WI 53202

Tel: 414.297.5612

rcasper@foley.com

S. Wayne Rosenbaum

Partner

402 W. Broadway, Ste 2100

San Diego, CA 92101

Tel: 619.685.6413

srosenbaum@foley.com