

Cautionary Tales in Food Labeling: California Prop. 65 Compliance, Enforcement Trends and Defense Strategies

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Prop. 65 Food Litigation

- Background
- New Warning Regulations
- Responsibility for Warnings
- Pesticides and Herbicides
- Enforcement Trends and Defenses
 - Acrylamide in Food, Coffee
 - Lead in Food
- PFOs/PFOAs
- Beyond Prop. 65

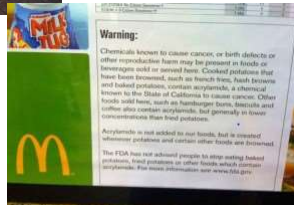
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Prop. 65 Background

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Prop. 65 Background



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Proposition 65

- Prohibits “knowing and intentional” exposure to more than 930 chemicals without first providing a “clear and reasonable” warning
- Cal. Health & Safety Code § 25249.6

WARNING

**This Product Contains
A Chemical Known To
The State Of
California To Cause
Cancer.**

List of chemicals at <https://oehha.ca.gov/proposition-65/proposition-65-list>

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Proposition 65 Enforcement

- Attorney General
- District and City Attorneys
- Private Enforcers
 - Must serve 60-day notice on violator, all of above <https://oag.ca.gov/prop65/60-day-notice-search>
- Amendment in October 2017
 - Codifies AG's practice of notifying enforcers when 60-day notice lacks merit.
 - Puts burden on enforcers to demonstrate documents supporting certificate of merit are not discoverable.



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Proposition 65 Penalties

- **Injunctions**
- **Penalties of up to \$2,500 per day for each violation**
- **Attorneys' fees**
- **Settlement payments in 2016 totaled \$30.2 million**

Enforcer	Settlements	Total	Average
CEH	93	\$4,028,282	\$43,315
Chanler	242	\$7,471,461	\$30,874
CAG	71	\$4,377,000	\$61,648
Custodio & Dubey	75	\$1,115,750	\$14,877
ERC	55	\$4,960,600	\$90,193
Shefa	31	\$1,011,350	\$32,624
Brodsky & Smith	99	\$2,469,474	\$24,944

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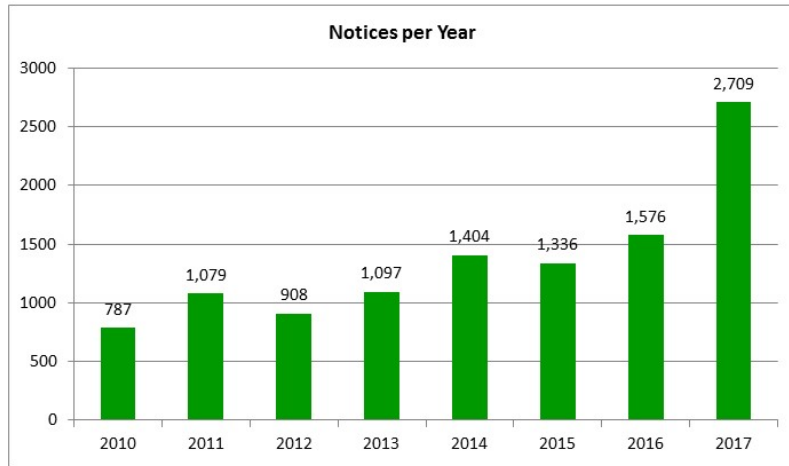
Defenses

- **No “knowing and intentional exposure”**
 - Must stop selling after receipt of 60-day notice
- **No exposure above “safe harbor levels”**
 - List at <http://oehha.ca.gov/prop65/pdf/P65safeharborlevels040116.pdf>
 - **No Significant Risk Levels for Carcinogens:** No more than 1 excess case of cancer in a population of 100,000 over 70 years
 - **Maximum Allowable Dose Level for Reproductive Harm:** No observable effect level at x 1,000 product concentration
- **Chemicals are naturally occurring**
 - Present solely as a result of absorption from the environment in which the food is raised or grown.
 - Not feasible to reduce.
- **Cooking**

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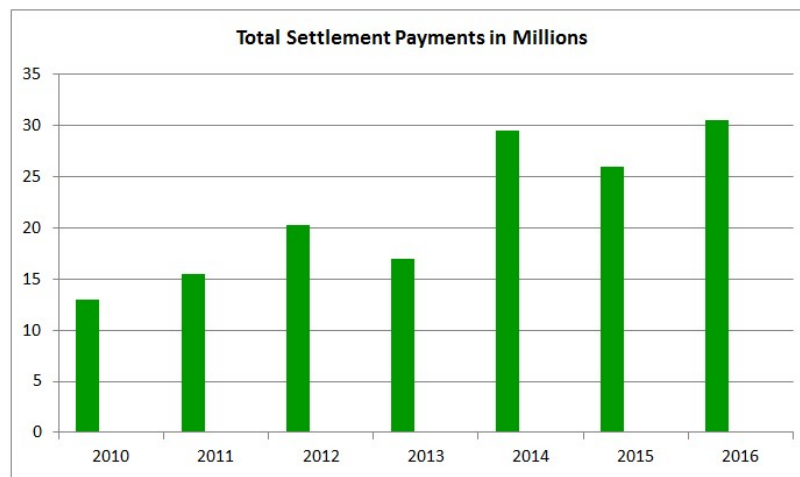
Prop. 65: 60-Day Notice Trends



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Prop. 65: Settlement Trends



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So why should you care?

- Growers and suppliers of agricultural products need to understand Prop 65 even if they don't label
- Prop 65 chemicals can be present:
 - Residual amounts of pesticides
 - Absorption from soil
 - Contamination during processing
- Depending on your contracts with your customers, you may have ultimate liability for enforcement actions based on Prop 65 chemicals in your products

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- Glyphosate in oat products
- Other pesticides
- Lead in chocolate
- Arsenic in rice
- Lead in balsamic vinegar
- Lead in baby food

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New Warning Regulations

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New Warning Regulations – Major Changes

- Warnings must include the triangular pictogram.
- The warning must identify at least one chemical for each type of harm (e.g. one carcinogen and one reproductive toxicant).
- Short form warnings are now allowed.
- Online warnings are now required.
- As discussed in more detail below, manufacturers and suppliers are now presumed to be responsible for providing product label warnings.



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New Warning Regulations

- **Effective August 30, 2018**
 - Businesses can comply with either warning in interim.
 - Products labeled with a warning prior to that date can continue to use the same warning.
- **Can continue to follow prior consent judgments**
 - Court approved consent-judgments only.
 - Only applies to parties.



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New Warnings - Food

- **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
- Where potential exposure is to both carcinogens and reproductive toxicants, list one example of both.
- Set apart in box. No smaller than other consumer information, and not smaller than 6-point type size.
- If consumer information is provided in another language, provide warning in that language.



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New Warnings – Food, Dietary Supplements

- Can use short form:
 - ⚠ **WARNING:** Cancer – www.P65Warnings.ca.gov
 - ⚠ **WARNING:** Reproductive Harm – www.P65Warnings.ca.gov
 - ⚠ **WARNING:** Cancer and Reproductive Harm – www.P65Warnings.ca.gov
- Can appear on label, packaging, shelf signs.
 - Shelf signs must be product specific and at each point of display.
- Can be received through electronic device.

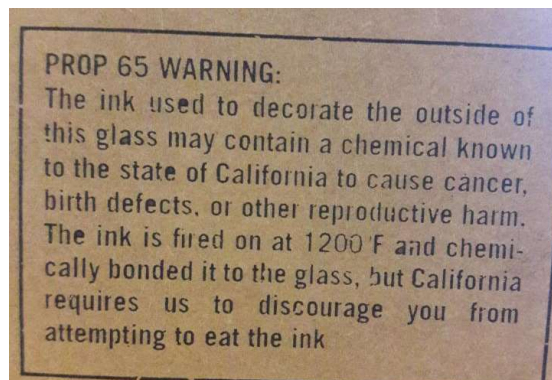


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New Warnings


- Supplemental information permitted if it identifies the source of the exposure or how to reduce exposure.



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New Warnings – Online

- Warning required on product display page, or
- Through hyperlink using word “**WARNING**,” or
- Prior to completing purchase.
 - Can be on pop-up triggered by entry of California address.
 - But must be a product specific warning
- Where short form is used on product, same warning can be used online.
 -  **WARNING:** Cancer – www.P65Warnings.ca.gov
- **Catalogs:** Warning must be clearly associated with the product that contains the listed chemical.

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New Warnings – Online

- Retailers should specify procedures for notice and receipt of warnings, including warning image.
- Manufacturers should seek carve out from defense and indemnity provisions where retailers fail to post warnings.

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Responsibility for Providing Warnings

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Warnings – Who's Responsible?

- **Statute:** Anyone who causes exposure:
 - Suppliers
 - Manufacturers
 - Distributors
 - Retailers often named as defendants, tender upstream
- **New regulations:** Manufacturer primarily responsible.
 - Limits retailer responsibility
 - For example, private label products
 - Provides way for manufacturer to shift responsibility back to retailer



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Warnings – Who's Responsible?

- **Manufacturers can shift burden to retailers**
 - Provide annual written notice specifically identifying products requiring warnings
 - Obtain confirmation of receipt
 - Supply all warning materials
 - shelf signs
 - sticker labels
- **Parties can allocate burden contractually**
 - Purchase order terms and conditions, vendor guide
 - Party with most bargaining power
 - Usually retailer saying don't send shelf warnings, stickers



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Warnings – Who's Responsible?

- **Requests for online warnings**
- **Requests for certification of compliance**
 - Retailers to distributors, manufacturers
 - Manufacturers to suppliers
- **How to respond:**
 - Knowledge of exposure
 - Consider testing
 - Market for product
 - Relationship with manufacturer



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Herbicides & Pesticides

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Glyphosate

- Listed as a carcinogen on July 7, 2017, based on IARC's determination that it is probably carcinogenic.
- OEHHA has proposed a NSRL of 1.1 mg/day, but it has not been adopted yet.
- Warning requirement took effect on July 8, 2018, but have been enjoined as discussed below.
- To date there have been no 60-day notices served, and glyphosate is not included in the list of regulated chemicals on the Attorney General's 60-day notice list



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Glyphosate – Legal Challenge

- Monsanto and several agricultural groups filed a suit challenging the listing and the requirement that a warning be provided.
- The Court denied the request to enjoin the listing, finding that 1) the listing was government speech and not compelled private/corporate speech, and 2) the warning requirement and not the listing is what creates the likelihood of irreparable harm.
- The Court granted a preliminary injunction against the warning requirement.
 - The Court held that “given the heavy weight of evidence in the record that glyphosate is not in fact known to cause cancer, the required warning is factually inaccurate and controversial,” and violated the regulated entities’ First Amendment right to free commercial speech. *National Association of Wheat Growers v. Lauren Zeise*, February 26, 2018, Docket no. 75, 2:17-cv-2401-WBS.
- The case is stayed pending the 9th Circuit’s rulings in two cases that may modify the standard for first amendment corporate speech claims.

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Glyphosate in Oat Products



- The Environmental Working Group released a report on August 15, 2018, which included test results showing varying levels of glyphosate in oat cereals, oatmeal, granola, and snack bars.
- 43 out of 45 conventional oat products had some amount of the chemical, while 5 out of 16 organic products had a detectable level.
- The “safe harbor” concentration level applied by EWG is not the Prop 65 safe harbor level that has been proposed by OEHHA, it was one hundred times more conservative.

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Other Herbicides, Fungicides

- **Tetrachlorvinphos :**
 - Pesticide used on fleas and ticks on livestock.
 - Two notices for flea collars (later withdrawn).
- **Malathion :**
 - Pesticide in agriculture, landscaping, and mosquito control.
 - Nineteen notices for white bread, cannabis, vape products.
 - Many withdrawn at AG's instruction for insufficient evidence.
 - NSRL set this year at 180 ug/day
- **Chlorothalonil:**
 - Multi-purpose fungicide.
 - Twelve 60-day notices.
 - But last one was in 2010

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Other Herbicides, Fungicides

No 60-day notices yet

- **Sedaxane:** Seed treatment fungicide.
- **Atrazine:** used in growing corn and sugarcane.
- **Propazine:** used for sorghum crops.
- **Simazine:** used in growing grapes, apples, citrus, corn, wheat.
- **Parathion:** used on fruit, wheat, vegetables, nut crops.

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What's on the Horizon

- **Chlorpyrifos**
 - Listed as a carcinogen.
 - Warning requirement takes effect on December 15, 2018.
 - An insecticide used primarily to control foliage and soil-borne insect pests on a variety of food and feed crops.

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Safe-Harbor Warning for Pesticides

- **Amendment to Safe-Harbor Warnings for Pesticides**
 - Pesticides and herbicides labels are heavily regulated by EPA and some state pesticide departments, which must review and approve labels.
 - Previously, approval of labels that included a Prop. 65 warning was being denied because of the use of word “WARNING”.
 - OEHHA has proposed an amendment to the warning regulations to allow use of word “ATTENTION” or “NOTICE” for pesticides, rather than “WARNING.”

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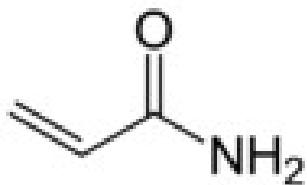
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Acrylamide in Food

Formed from Maillard reaction, by heating sugars to high temperatures



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- **High-carbohydrate foods**
 - French fries
 - Potato and veggie chips
- **Grain-based foods**
 - Cookies
 - Crackers
 - Cereals
 - Breads and bagels
- **Grilled meat**
- **Fruits**
 - Olives
 - Prunes
- **Coffee**

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Acrylamide in Foods

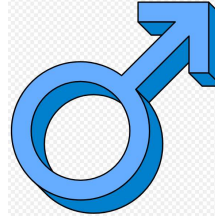
- **Carcinogen**

- NSRL is .2 ug/day



- **Reproductive Harm**

- MADL is 140 ug/day



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Acrylamide in Foods

- **FDA:**

- Prop. 65 warnings might “confuse and potentially mislead consumers, both because the labeling would be so broad as to be meaningless and because the risk of consumption of acrylamide in food is not yet clear.”

- **OEHHA**

- Considered, but has withdrawn proposal to
 - Raise NSRL to 1 ug/day
 - Limit in breads and cereals to 200 ppb
 - Create separate warning for acrylamide

WARNING:
Baking, roasting, frying and toasting starchy foods forms acrylamide, a chemical known to the State of California to cause cancer.
Given what is currently known about exposures to acrylamide in foods, the U.S. Food and Drug Administration (FDA) advises consumers to continue to eat a balanced diet, choosing a variety of foods that are low in trans and saturated fat and rich in high-fiber grains, fruits and vegetables.
Levels of acrylamide in foods vary and may be reduced by avoiding excessive browning or crisping of some foods. Boiling or steaming foods does not form acrylamide.
For more information on foods that contain acrylamide, visit the following websites: WWW.OEHHA.CA.GOV or WWW.FDA.GOV

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Acrylamide in Food

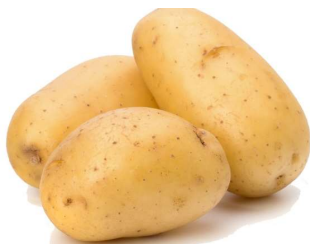
- **400 60-day notices served**
- **Recent potato/veggie chip and snack food cases**
 - Limits of average 350 ppb for veggie, 281 ppb potato products
 - Trial set for January 2019
 - Focus on whether exposure exceeds safe harbor level when average consumption over weeks.
 - Next phase might raise cooking defense.

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FDA Guidance for Reducing Acrylamide

- **Potatoes**
 - Variety: low in reducing sugars
 - Optimize maturity
 - Avoid bruising, sprouting
 - Avoid prolonged cold in storage, handling
- **Cereal-based foods**
 - Use wheat varieties low in asparagine
 - Rice for wheat



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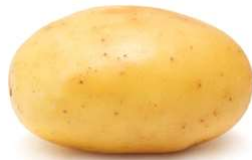


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Acrylamide in Foods

- **New potato varieties**

- Six new varieties with lower asparagine, reducing sugars
- Reduced cold-induced sweetening (CIS)
 - Starch converts to reducing sugars during cold storage



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- **New technologies**

- Vacuum frying
- Increase moisture while decreasing temperature



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Acrylamide in Food

- California Court of Appeals has held Prop. 65 warning requirement preempted as to cereal by FDA policy of encouraging consumption of whole grains.

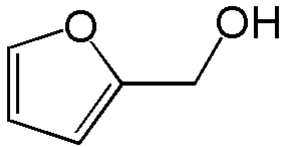


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Furfuryl Alcohol

- **Forms during Maillard reaction, much like acrylamide.**



- Baked goods
- Coffee
- Pasteurized milk
- Wine, beer, and spirits
- Ice cream
- Juice beverages
- Toasted nuts
- Rice cakes

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Furfuryl Alcohol

- **Carcinogen**
- **Warning requirement: September 2017**
- **No safe harbor level**
 - Any amount can trigger warning requirement
- **60-day notices: 7**
 - Dried meat: withdrawn
 - Potato and sweet-potato snack foods
 - Potato bread
 - Pretzels
- **No complaints or settlements**
 - No chemical limits
 - Consider pursuing SUD

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Warning for Acrylamide / Furfuryl Alcohol

WARNING: Consuming this product can expose you to chemicals, including acrylamide, which 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.

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Acrylamide in Coffee



- The Council for Education and Research on Toxics issued 60-day notices to over 90 members of the ready to drink coffee industry.
- Some of the industry members settled, but roughly 90 defendants refused to settle, and in 2010 CERT filed a complaint in LA Superior Court.
- The issue is that acrylamide is a natural byproduct of the coffee roasting process, and there is no way to reduce the amount of acrylamide produced to levels that would meet the NSRL.

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Acrylamide in Coffee – Phase I

- The trial was bifurcated, and the Court held the first bench trial in 2014-2015.
- In Phase I Defendants argued that the level of acrylamide in coffee should not be found to be in excess of the NSRL because all of the other chemicals in coffee combine to counteract any carcinogenic effect of the acrylamide.
- Defendants also argued that under the First Amendment they could not be required to post a warning that they felt was inaccurate.
- The Court found in favor of Plaintiff on both of the arguments.

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Acrylamide in Coffee – Phase II

- Trial on the second phase of the case ended in October 2017.
- Defendants argued that the acrylamide is created during the process that is necessary to make the food palatable or safe to eat, and should therefore be subject to a higher NSRL.
 - This is often described as the “cooking provision.”
- The Court once again ruled in favor of Plaintiff.



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Acrylamide in Coffee – OEHHA’s Proposed Exemption

- On June 15th OEHHA issued a notice of proposed rulemaking to exempt coffee from the warning requirement when the Prop. 65 chemicals are created “as part of and inherent in the processes of roasting coffee beans and brewing coffee.”
- Defendants in the litigation have moved for a stay pending the issuance of the proposed rule.
- Take Away – Food product retailers face significant challenges in convincing courts to apply the potential exemptions

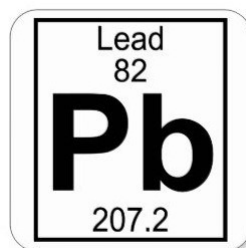
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Lead

- **Nearly 10,000 60-day notices**

- Balsamic vinegar
- Rice
- Cereal
- Seaweed
- Fruits and fruit juice
- Chocolate
- Infant formula

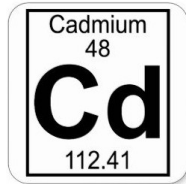


- **Carcinogen**
 - NSRL is 15 ug/day
- **Reproductive toxicant**
 - MADL is .5 ug/day

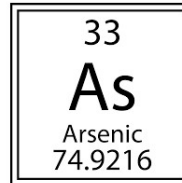
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Cadmium, Arsenic



- **Cancer:** NSRL .05 ug/day
- **Reproductive Harm:** MADL 4.1 ug/day
- **60-day notices:** 838



- **Arsenic**
- **Cancer:** NSRL
 - .06 ug inhalation
 - 10 ug/day
- **60-day notices:** 622

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Lead

- **Naturally occurring?**
 - Defendant's burden
 - Levels absorbed from environment
 - Not feasible to reduce



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Lead

- Early 60-day notices for lead in chocolate.
 - AG's office issued opinion lead naturally occurring.
- 2015 60-day notices:
 - AG's office retreated from naturally occurring position
 - **Consent judgment** approved February 14, 2018.
 - Limits range from .100 ppm for 65% cacao to .225 ppm for 95%



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Lead

- **Beech-Nut:** Defendants failed to show naturally occurring
- **Exposure was below safe harbor level**
 - Test results averaged across lots
 - Consumption based on NHANES instead of serving size
 - Average exposure over several weeks, instead of one day



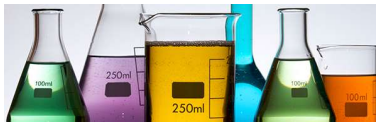
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Challenges to Lead MADL

- **Mateel v. OEHHA**

- Challenged MADL as not based on level at which no observable effect exists.
- Mateel lost trial, appealed.
- Court of Appeal affirmed in September 2018.



- **OEHHA Proposal:**

- Lower MADL to .2 ug/day
- Clarify based on single-day exposure, not averaging
- Prohibit averaging test results across lots.
- Set naturally occurring levels of arsenic, lead in some foods.
 - So far, only for arsenic in rice.
 - White rice: 80 ppb
 - Brown rice: 170 ppb

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Lead Warning Covers All Chemical Exposures

WARNING: Consuming this product can expose you to chemicals, including lead, which 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.

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On The Horizon

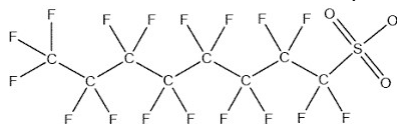
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PFAs – On the horizon

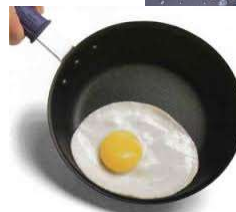
- Perfluorooctanoic Acid (PFOA)



- Perfluorooctane Sulfonate (PFOS)



- OEHHA listed PFOA and PFOS on November 10, 2017, based on an EPA drinking water health advisory.
- No safe harbor levels.



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PFAs – Food Packaging

- They were historically used to manufacture a variety of products, including certain types of water/grease proof food packaging.
- Both chemicals have been phased out of production, so why is this an ongoing concern?
 - 1) The chemicals are persistent, and may still be present at latent levels in manufacturing equipment, process water, etc.
 - 2) Replacement chemicals are sometimes contaminated with PFOA and PFOS, so switching to new PFAs may not solve the Prop 65 liability problem.

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PFAs – Federal and State Regulation



- Washington packaging law – HB-2658
 - Bans the use of “perfluoroalkyl and polyfluoroalkyl substances” in food packaging made from natural fibers.
 - The ban goes into effect in 2022 or two years after the Washington Department of Ecology determines that safer alternatives exist.
- DTSC has listed Food Packaging as a Priority Product under its Safer Consumer Products regulations, specifically noting Washington’s packaging law. This suggests that California may follow suit and regulate the use of a wide variety of PFAs in food packaging.
- EPA also recently held a stakeholder summit to discuss PFAs and their regulation. If EPA issues regulations or advisories regarding other PFAs, Prop 65 will adopt those listings.

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Questions

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