



Dangerous Coffee, Herbicides for Breakfast, and More: Welcome to Food Court

Speakers

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Materials

Program PowerPoint Presentation

Dorsey eUpdate: *Prop 65 Developments Relevant to the Food & Beverage Industry: Changes On Three Important Fronts*, Mark Kaster, Kent Schmidt and Alexandra Krasovec (July 2, 2018)

Available at: <https://www.dorsey.com/newsresources/publications/client-alerts/2018/07/prop-65-developments-food-and-bev-industry>

FDA Statement: Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's Support for Exempting Coffee from California's Cancer Warning Law (August 29, 2018)

Available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm618883.htm>

Food Risk Summit

Dangerous Coffee, Herbicides for Breakfast, and More: Welcome to Food Court

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California's Prop 65 – Legislative Developments



Brief Background on the Law (Cal. Health & Safety Code Section 25249.5)

- **The Unusual Predicate:** Use of chemicals in products not prohibited, but a warning label is required.
- **Cancer and Reproductive Harm:** Dual focus of the law.
- **The Growing List:** 30 chemicals in 1987, over 900 today.
- **The Penalty (\$2,500):** Each exposure a separate violation.
- **The Thriving Cottage Industry:** A significant number of lawsuits continue to be filed by individuals and entities in the public interest.
- **The “Safe Harbor” Concepts**
 - MADL (Maximum Allowable Dose Level) for reproductive toxins: identifies the exposure level and divides that figure by 1,000 to establish a margin.
 - NSRL (No Significant Risk Level) cancer: a safe harbor based on one cancer out of 100,000 exposed for a 70-year period.
- **The Burden Shifting:** Once the presence of a chemical or carcinogen is established, burden shifts to defendant to show no warning required.
- **Transparency into Settlements:** Court approval required, Attorney General notification, amounts reported to the OEHHA, a searchable database.

California's Prop 65 – Regulatory Developments



- **OEHHA's Concerns and Objectives**
 - Over-warning phenomenon
 - Questions on methods and content of warning including greater specificity as to the nature of the exposure
 - Who is culpable and who is left holding the bag? Apportioning among parties in the distribution chain
- **New Regulations Became Effective August 30, 2018**
 - **Methods and Contents of Warnings (Section 25601*)—The New “Safe Harbors”**
 - Not required to use the warning methods but will be deemed a “safe harbor” to liability.
 - Two warning schemes: on product warning labels and other warnings including packaging, website and catalogues
 - Specificity required on all warnings except product labels
 - **Apportionment of Liability (Section 25600.2)**
 - Product manufacturers, producers, packagers, importers, suppliers or distributors are primarily responsible for providing warnings.
 - A retailer following reasonable directives of a manufacturer now has certain “safe harbors” from Prop 65 liability. (25600.2)
 - Agreements between the parties in the distribution chain.
 - **Industry Specific Safe Harbors Including Food and Beverage**

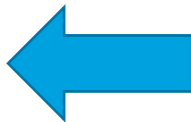
Section refers to Title 27, Article 6, California Code of Regulations.

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California's Prop 65 – Regulatory Developments



WARNING
“Consuming this product can expose you to chemicals [include name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information to www.P65Warnings.ca.gov/food”



- **New Regulations Specifically Applicable to Food & Beverage**
 - **Food Exposure Warnings – In General**
 - **Methods of Transmission (25607.1)**
 - Where warning on a food product label, must be set off from other information and in a box. (25607.1(a))
 - If another language used on a sign, label or shelf tag, the warning must also be provided in that language. (25607.1(b))
 - **Content requirements (Section 25607.2)**
 - This is the warning for carcinogens.
 - Similar for reproductive toxicants.
 - If both exist, both must be listed.
 - Consistent with regulative changes requiring greater specificity in other contexts.

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California's Prop 65 – Regulatory Developments

- **New Regulations Specifically Applicable to Food & Beverage**
 - **Alcoholic Beverage Exposure Warnings – Methods of Transmission (Section 25607.3) and Content (Section 25607.4)**
 - **Food and Non-Alcoholic Beverage Exposure Warnings for Restaurants – Methods of Transmission (Section 25607.5)**
 - (1) An 8½ by 11 inch sign, printed in no smaller than 28-point type placed so that it is readable and conspicuous to customers as they enter each public entrance to the restaurant or facility where food or beverages may be consumed.
 - (2) A notice or sign no smaller than 5 by 5 inches, printed in no smaller than 20-point type placed at each point of sale so as to assure that it is readable and conspicuous.
 - (3) A warning on any menu or list describing food or non-alcoholic beverage offerings, in a type size no smaller than the largest type size used for the names of general menu items.
 - (b) The warning must be provided in English and in any other language used on other signage or menus provided on the premises.
 - **Food and Beverage Exposure Warnings for Restaurants – Content (Section 25607.6)**
 - (1) The word "WARNING" in all capital letters and bold print.
 - (2) The words, "Certain foods and beverages sold or served here can expose you to chemicals including acrylamide in many fried or baked foods, and mercury in fish, 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/restaurant."



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California's Prop 65 – The Ingredient Conundrum

Two Issues: Occupational Exposures and Anticipated Concentration Levels

Q14: If a company manufactures component parts or ingredients that are sold in bulk to other manufacturers or formulators, how can it comply with the requirement to provide a warning, especially if the need for a warning depends on the concentration or the manner of use of the listed chemical in the final product?

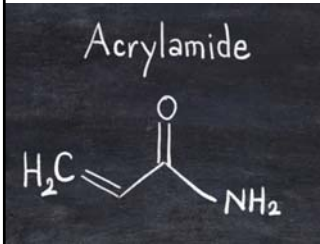
A14: A company that manufactures component parts or ingredients that include listed chemicals can comply with the obligation to warn persons who can be occupationally **exposed to the bulk product** by providing warnings consistent with Section 25606. The company would only have responsibility for a consumer warning if it has knowledge that the end use of the component part or ingredient can **expose a consumer to a listed chemical** (See FSOR, p. 138). For example, if a manufacturer of a food ingredient knows that the ingredient is typically used in certain types of prepared foods and could thereby result in an exposure under the Act, then the ingredient manufacturer should provide the warning to the product manufacturer [Section 25600.2]. The product manufacturer is then responsible for determining whether the product they are manufacturing causes an exposure to the chemical at a level that requires a warning. If so, the product manufacturer is responsible for passing the information along to its customers or the product retailer [Section 25600.2]. In such a situation, the ingredient manufacturer may also choose to work with the product manufacturer to evaluate whether the product should have a warning and may **enter into a contract with product manufacturers to ensure that the warning is transmitted to the retailer and ultimately the consumer** [Section 25600.2(i)].

OEHHA, QUESTIONS AND ANSWERS FOR BUSINESSES (July 2018)



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California's Prop 65 – The Five Big Issues



- **Acrylamide**

- A chemical compound with the chemical formula C_3H_5NO .
- Naturally occurring in the process of baking, frying or roasting plant-based foods.
- The MADL for acrylamide is 140 micrograms a day.
- Food Focus
 - Presence in coffee has been the focus for many years. Significant loss for industry in Los Angeles Superior Court followed by an OEHHA walk-back late in the year—not required for coffee.
 - The French fry, potato chip/KFC vs. the coffee
 - The FDA Guidance provides information to help growers, manufacturers, and food service operators reduce acrylamide levels in certain foods.”



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California's Prop 65 – The Five Big Issues



- **Glyphosate**

- A chemical used in herbicides such as Roundup.
- Concerns raised in Europe in 2015--“probably carcinogenic in humans”.
- Listed on Prop 65 list in 2017 meaning the standard “known to the State of California to cause cancer” was purported met.
- Trace amounts of glyphosate can found in soy, corn and corn oil, nuts, beets, beet sugar, carrots, grains
- In July 2018, OEHHA Set a NSRL of 1100 micrograms per day for glyphosate
- \$289 million personal injury verdict in San Francisco in August 2018 has only added to the attention to the issue and brought a wave of lawsuits. (Bayer, which acquired Monsanto, reported in August 8,000 pending lawsuits)
- Parallel lawsuits with mixed results.
 - *Monsanto Co. v. Office of Environmental Health Hazard Assessment* (“OEHHA”), No. 16-CE CG 00183 (Fresno County Superior Court),
 - Argument improper delegation “authoritative body” International Agency for Research on Cancer, forced speech.
 - Challenges unsuccessful at trial court, Court of Appeal and review denied by Cal. Supreme Court
 - *National Association of Wheat Growers et al v. Lauren Zeise, director of OEHHA, et al, U.S. District Court, Eastern District of California, No. 17-at-01224.*
 - Adopted the force speech argument.



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California's Prop 65 – The Five Big Issues

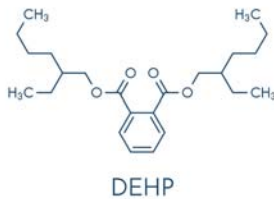


"Many food and beverage cans have linings containing bisphenol A (BPA), a chemical known to the State of California to cause harm to the female reproductive system. Jar lids and bottle caps may also contain BPA. You can be exposed to BPA when you consume foods or beverages packaged in these containers. For more information go to: www.P65Warnings.ca.gov/BPA.

- **Bisphenol A (BPA).** "BPA is a widely used chemical. It is used in some protective coatings, including some linings that prevent rust, corrosion, and contamination in metal food and drink cans. Some jar lids and bottle caps also have these linings." OEHHA Website
 - **Safe Harbor: 25607.30:** Applicable to "canned and bottled foods and beverages" which means "foods and beverages packaged in hermetically sealed, durable metal or glass containers, including, but not limited to, those containing fruits, vegetables, soups, pasta products, milk, soda, and alcoholic beverages."
 - **Two Options**
 1. **Product Label:** "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm" (25607.30(a)(1)(A))
 2. **Point of Sale Warnings:** Must provide written notice and the signs at no costs. (25607.30(a)(1)(B))



California's Prop 65 – The Five Big Issues



- **DEHP (Di(2-ethylhexyl)phthalate):**
 - "DEHP belongs to a family of chemicals called phthalates, which are added to some plastics to make them flexible." OEHHA Website
 - Virtually eliminated from most food packaging, but may be detected in food that has come into contact with certain plastic during processing and packaging.
 - "Low levels of DEHP have been detected in some foods that have been in contact with plastics during processing and packaging." OEHHA Website
- **Lead:** An "oldie but goodie" in Prop 65. OEHHA Warns that lead has been found in "[s]ome candies and spices from Mexico and Asia, some balsamic vinegars, some brightly colored traditional remedies such as Azarcon and Greta, and some dietary supplements" Naturally occurring is not a defense.

The Future of Prop 65

- **The FDA's Shot Across the Bow to California**
 - August 29, 2018 letter from FDA to California regarding acrylamide.
 - From the FDA's website:

The FDA previously wrote to California stating our concerns about acrylamide warnings for foods because such warnings may mislead consumers about the risks posed by foods containing acrylamide and encourage consumers to alter their diets in ways that may not benefit their health. A prime example is whole grain foods. We recognize that some of these products may contain acrylamide. **But we also know that consumption of whole grains is beneficial for health and nutrition. Labeling whole grain foods with a cancer warning may cause American consumers to avoid foods that would have a benefit to their health, including avoiding foods that may reduce cancer risks.**
 - Do Prop 65 warnings cause consumers to avoid the very foods they need according to FDA nutritional recommendations ?
- **California Will Continue to Look to European Regulators**
- **Growing Consensus for Uniform Standards Over Patchwork of State Regulations**
- **Laws Similar to California's Prop 65 are Sprouting up in Other Jurisdictions.**
- **Preemption Options to the FDA and Congress**
- **Court's More Sympathetic to Responsible Defendants, Questioning Junk Science**



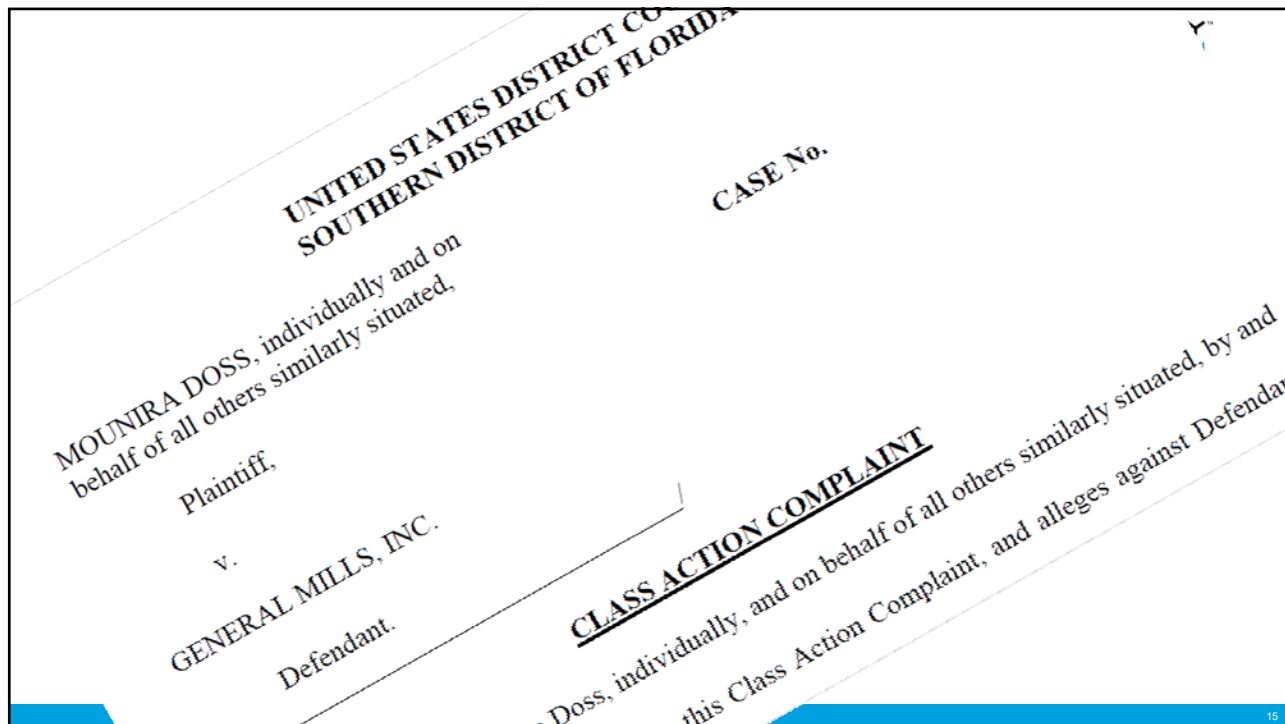
No Physical Harm Labeling Cases

- *Allred v. Frito-Lay N. Am., Inc.*, 2018 WL 1185227, 2018 U.S. Dist. LEXIS 37617 (S.D. Cal. Mar. 7, 2018)
- *Allred v. Kellogg Co.*, 2018 WL 1158885, 2018 U.S. Dist. LEXIS 38576 (S.D. Cal. Feb. 28, 2018)
- *Fitzhenry-Russell v. Dr Pepper Snapple Grp., Inc.*, 2017 WL 4224723, 2017 U.S. Dist. LEXIS 155654 (N.D. Cal. Sept. 22, 2017)
- *In re General Mills Glyphosate Litig.*, 2017 WL 2983877, 2017 U.S. Dist. LEXIS 108469 (D. Minn. July 12, 2017)
- *Krommenhock v. Post Foods, LLC*, 2018 U.S. Dist. LEXIS 42938 (N.D. Cal. Mar. 15, 2018)
- *Coe v. General Mills, Inc.*, 2016 WL 42008287, 2018 U.S. Dist. LEXIS 105769 (N.D. Cal. Aug. 10, 2016)

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\$289 Million

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Doss v. General Mills, 0:18-cv-61924 (S.D. Fla.)

30,000 ppb

EPA threshold for glyphosate in cereal

470 ppb – 530 ppb

Alleged EWG test results

160 ppb

EWP “child-protective health benchmark”



Competitor-Driven Cases

- ***Tortilla Factory, LLC v. Rowdy Mermaid Kombucha LLC, 2:18-cv-02984 (C.D. Cal.)***
- ***Tortilla Factory, LLC v. Better Booch, LLC, 2:18-cv-02980 (C.D. Cal.)***
- ***Tortilla Factory, LLC v. Humm Kombucha, LLC, 2:17-cv-09092 (C.D. Cal.)***
- ***Tortilla Factory, LLC v. Health Ade, LLC, 2:17-cv-09090 (C.D. Cal.)***

Does *Bristol-Myers Squibb* Apply to Class Actions?

[T]he nonresidents were not prescribed Plavix in California, did not purchase Plavix in California, did not ingest Plavix in California, and were not injured by Plavix in California. The mere fact that other plaintiffs were prescribed, obtained, and ingested Plavix in California – and allegedly sustained the same injuries as did the nonresidents – does not allow the State to assert specific jurisdiction over the nonresidents' claims.

Bristol-Myers Squibb Co. v. Superior Court, 137 S.Ct. 1773, 1781 (2017)

Does *Bristol-Myers Squibb* Apply to Class Actions?

[R]estrictions on personal jurisdiction “are more than a guarantee of immunity from inconvenient or distant litigation. They are a consequence of territorial limitations on the power of the respective States.” “[T]he States retain many essential attributes of sovereignty, including, in particular, the sovereign power to try causes in their courts. The sovereignty of each State . . . implie[s] a limitation on the sovereignty of all its sister States.” And at times, this federalism interest may be decisive. As we explained in *World-Wide Volkswagen [v. Woodson]*, 286 U.S. 291, 294 (1980), “[e]ven if the defendant would suffer minimal or no inconvenience from being forced to litigate before the tribunals of another State; even if the forum State has a strong interest in applying its law to the controversy; even if the forum State is the most convenient location for litigation, the Due Process Clause, acting as an instrument of interstate federalism, may sometimes act to divest the State of its power to render a valid judgment.”

Bristol-Myers Squibb Co. v. Superior Court, 137 S.Ct. 1773, 1780-81 (2017) (internal citations omitted)

Does *Bristol-Myers Squibb* Apply to Class Actions?

YES:

Chavez v. Church & Dwight Co., 2018 WL 2238191, 2018 U.S. Dist. LEXIS 82642 (N.D. Ill. May 16, 2018)

In re Dental Supplies Antitrust Litig., 2017 WL 4217115, 2017 U.S. Dist. LEXIS 153265 (E.D.N.Y. Sept. 20, 2017)

Practice Mgmt. Support Servs. V. Cirque du Soleil, Inc., 2018 WL 1255021, 2018 U.S. Dist. LEXIS 39754 (N.D. Ill. Mar. 12, 2018)

DeBernardis v. NBTY, Inc., 2018 WL 461228, 2018 U.S. Dist. LEXIS 7947 (N.D. Ill. Jan. 18, 2018)

Does *Bristol-Myers Squibb* Apply to Class Actions?

NO:

Fitzhenry-Russell v. Dr Pepper Snapple Grp., Inc., 2017 WL 4224723, 2017 U.S. Dist. LEXIS 155654 (N.D. Cal. Sept. 27, 2017)

Molock v. Whole Foods Mkt., Inc., 297 F. Supp. 3d 114 (D.D.C. Mar. 15, 2018), *certified for interlocutory appeal*, 2018 U.S. Dist. LEXIS 97428 (June 11, 2018) (“The cases holding that *Bristol-Myers Squibb* applies to claims of nationwide class members are well-reasoned and do not lack persuasive power.”)

In re Morning Song Bird Food Litig., 2018 WL 1382746, 2018 U.S. Dist. LEXIS 44825 (S.D. Cal. Mar. 19, 2018)

Casso’s Wellness Store & Gym, LLC v. Spectrum Lab. Prods., Inc., 2018 WL 1377608, 2018 U.S. Dist. LEXIS 43974 (E.D. La. Mar. 19, 2018)

Standing to Pursue Injunctive Relief?

- *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992)
- *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139 (2010)
- *Davidson v. Kimberly-Clark Corp.*, 873 F.3d 1103 (9th Cir. 2017) (“*Davidson I*”)
- *Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956 (9th Cir. May 9, 2018) (“*Davidson II*”)

Brady v. Bayer Corp., 2018 WL 4275356, 2018 Cal. App. LEXIS 800 (Cal. Ct. App. Sept. 7, 2018)

“Themes” for analyzing misleading label claims under CRLA and UCL

1. “Common Sense”
2. “Literal Truth/Literal Falsity”
3. “The Front-Back Dichotomy”
4. “Brand Names Misleading in Themselves”

Gift on Class Certification?

Questions

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July 2, 2018



Prop 65 Developments Relevant to the Food & Beverage Industry: Changes On Three Important Fronts

Mark Kaster, Kent Schmidt and Alexandra Krasovec

Introduction

The perils of Prop 65 claims are well-known to most food and beverage companies around the world.¹ Through its one-of-a-kind labeling law, California regulates thousands of businesses that sell consumer goods to Californians, whether through e-commerce or retail outlets in the state.² A product, including a food or beverage, that contains a chemical or carcinogen known to the State of California to cause cancer or reproductive toxicity must be accompanied by a written warning informing the consumer of the putative risks.³ Each year, hundreds of Prop 65 “60-day notice letters” arise from a cottage industry of private (“bounty hunter”) enforcers. The vast majority of these claims result in court-approved settlements that include penalties and substantial attorney fee awards.

This year marks a period of seismic shifts in the Prop 65 landscape, perhaps the most significant changes since the amendments to the law in 2001. The changes will impact many food and beverage companies in particular, as well as other industries and sectors. Regulators and courts are making a series of adjustments as to how this unique regulatory scheme applies to the food and beverage industry.

In the long-term, these changes may bring greater clarity to the law, enhancing companies’ ability to achieve compliance and avoid claims. But in the near term, there are many unanswered questions. Three primary areas of development are of particular importance to the food and beverage industry.

A Break for the Coffee Industry

The first Prop 65 development for the food and beverage industry is product specific—dark roast coffee. As has been widely publicized and watched, a lawsuit was brought in Los Angeles Superior Court to require a Prop 65 warning for the presence of acrylamide in dark roast coffee. The resulting ruling, issued by the court in February, sent a jolt to the coffee industry by agreeing with plaintiffs that a Prop 65 warning is required to inform consumers of traces of acrylamide in coffee.

The litigation was significant because, unlike most claims that are settled early on, the coffee industry pressed their defenses, pitting a common sense theory against what they contended was an unreasonable application of the regulation. They pointed to the fact that acrylamide is a

¹ The Safe Drinking Water and Toxic Enforcement Act of 1986, better known as Prop 65 is codified at Cal. Health & Safety Code § 25249.5 et seq.

² For an overview of the law, see LeftCoast Law Blog Post, *What is Prop 65?*

³ The current Prop 65 List of regulated substances is available on Cal OEHHA’s website.

naturally-occurring chemical reaction stemming from the process of roasting coffee beans. There is no way to eliminate this chemical reaction in the coffee roasting process. They further advanced the argument that coffee consumption is, on the whole, healthy, with many benefits to the body and these benefits outweigh the minimal and unsubstantiated risk that the smallest traces of acrylamide might present.

Judge Elihu Berle rejected each of these arguments, sending the industry reeling with how to address this new regulatory reality. Although many coffee shops in California had for years placed a small warning label at the point of sale, most in the industry are not keen on the idea of placing a warning label on coffee shipped to any consumer in California, to indicate that the product contains acrylamide, a chemical known to the State of California to cause cancer.

To the surprise of many, the California regulators intervened and agreed with the coffee industry. Although it still lists acrylamide as a carcinogen,⁴ OEHHA, the agency that promulgates regulations implementing Prop 65, announced on June 15, 2018, its intent to modify the regulations to clarify that Prop 65 warnings are not required for coffee despite the acrylamide that results from the roasting process: The proposed regulation states that “drinking coffee does not pose a significant cancer risk, despite the presence of chemicals created during the roasting and brewing process that are listed under Proposition 65 as known carcinogens . . . is based on extensive scientific evidence that drinking coffee has not been shown to increase the risk of cancer and may reduce the risk of some types of cancer.”⁵ This intervention is a refreshing change; as regulators do not typically side with industry, particularly after an unsuccessful challenge in the courts.

The sensibility of OEHHA’s rare move on acrylamide and coffee is apparent. Prop 65 is designed to cause industries to re-formulate products because the alternative of placing a warning label is not an attractive option. But naturally occurring chemicals such as acrylamide cannot be eliminated and the exposure levels are so small that an increased risk of cancer has not been shown. In other words, it is simply not possible to make a safer cup of coffee.

It remains to be seen whether this intervention represents a more sensible approach to the impact of Prop 65 regulations and whether this same course of action may be taken for naturally occurring chemicals in other types of food products.

Federal Court Intervention in Prop 65 Enforcement

While California regulators were overriding Judge Berle’s coffee decision, the California Attorney General was seeking to defend new Prop 65 regulations applicable to glyphosate actions in federal court. Glyphosate is a chemical used in certain herbicides. Effective July 7, 2017, California added glyphosate to its list of chemicals deemed to create a risk of cancer. The ramifications of adding glyphosate to Prop 65’s list were far reaching. Arguably, if a food product is made from crops treated with glyphosate, a warning label would be required.

⁴ See OEHHA’s Fact Sheet on Acrylamide.

⁵ Proposed OEHHA regulation clarifies that cancer warnings are not required for coffee under Proposition 65.

A number of organizations in the industry launched an attack on the glyphosate listing, advancing a creative legal argument.⁶ The legal theory was that, given the unsubstantiated claims relating to the risks of glyphosate, the addition of this chemical violated those companies' constitutional rights by constituting "forced speech" on a matter that was not purely factual and controversial under the First Amendment.⁷

U.S. District Court Judge William Shubb agreed, issuing an order earlier this year enjoining the addition of glyphosate. On June 12, 2018, he denied a motion for reconsideration, stating: "Given the evidence in the record, the court questions whether California has shown that requiring a Proposition 65 warning for glyphosate directly advances the law's stated interest in informing Californians about exposures to chemicals that cause cancer."⁸

Judge Shubb's ruling is a significant win for the food and beverage industry. It leaves open the possibility that other Prop 65 regulations, as applied, may be challenged if the risk is truly unsubstantiated by the government.

New Food and Beverage Regulations Relating to Notice

Against this backdrop of judicial developments for the food and beverage industry, a new dawn is breaking on the Prop 65 regulatory landscape. As of September 1, 2018, a series of regulations will be fully implemented, impacting business in general, but having particular application to the food and beverage product labels.

In 2016, California regulators enacted sweeping changes to the nature of the Prop 65 regulations. Up to this point, Prop 65 warnings could be general and non-specific, simply informing the consumer that the product contains a chemical or other substance known to the State of California to cause cancer or reproductive toxicity.⁹ For many products, the new regulations require greater specificity, identifying at least one of the Prop 65 listed chemicals or carcinogens. In addition, warnings labels must include reference to OEHHA's website (www.P65Warnings.ca.gov) as a resource for further information. Some warnings require a triangular warning symbol (a yellow triangle with an exclamation mark) to draw the attention of the consumer.

Additionally, the new regulations provide specially tailored warnings for particular types of exposures and products. There are new clarifications as to duties, as between manufacturers and retailers, and how parties in the chain of distribution can be insulated from risks by transferring responsibilities to others. There are also new regulations relating to when warnings must be provided in a language other than English.

It is important to understand that the new warning regulations are not mandatory but constitute a safe harbor. Businesses may comply with the statute by providing a warning that does not precisely match the safe-harbor language but should be prepared to defend that method of

⁶ *National Association of Wheat Growers et al v. Lauren Zeise, director of OEHHA, et al*, U.S. District Court, Eastern District of California, No. 17-at-01224.

⁷ The Court cited *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985).

⁸ June 12, Order, page 8.

⁹ OEHHA has published a side-by-side comparison of the old and new regulatory texts.

informing consumers of the risk. A business may argue that, in light of all relevant circumstances, the warning was reasonable and complied with the law.

In addition to the series of new generally-applicable regulations, there are a number of industry or product specific regulations. The following apply to the food and beverage industry:

- Food Exposure Warnings – Methods of Transmission (Section 25607.1)
- Food Exposure Warnings – Content (Section 25607.2)
- Alcoholic Beverage Exposure Warnings – Methods of Transmission (Section 25607.3)
- Alcoholic Beverage Exposure Warnings – Content (Section 25607.4)
- Food and Beverage Exposure Warnings for Restaurants – Methods of Transmission (Section 25607.5)
- Food and Beverage Exposure Warnings for Restaurants – Content (Section 25607.6)
- Warnings for Exposure to Bisphenol A from Canned and Bottled Foods and Beverages (25607.31)

In conclusion, now is a good time to re-examine Prop 65 compliance, best practices, and litigation avoidance strategies. A few steps are worth considering:

- Replacing general label warnings with language that satisfies the specificity required by the new regulations;
- Addressing upstream suppliers to ensure that they are complying with the requirements of Prop 65 and negotiating appropriate indemnity language in supply contracts;
- Analyzing downstream retailers and others in the chain of distribution which may have the ability to provide notice to consumers at the point of sale; and
- Testing products and addressing other exposure scenarios including environmental.

Even with the positive developments for the coffee industry on the acrylamide front and the win on the glyphosate warning, Prop 65 claims will continue to present a substantial regulatory and litigation risk for the food and beverage industry in the foreseeable future.

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FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's support for exempting coffee from California's cancer warning law

For Immediate Release

August 29, 2018

Statement

Ensuring that food is safe and truthfully labeled is one of our fundamental responsibilities at the U.S. Food and Drug Administration. Consumers deserve accurate information about the food they eat and how it can affect their health and nutrition. That's why Congress entrusted the FDA to serve as the nation's expert on food safety and labeling and to craft predictable, uniform federal requirements on matters within our jurisdiction. Consistent with that authority, we work to provide the best advice possible to Americans about the foods they eat based on the most recent scientific information, taking into account the food's benefits in addition to any potential health risks.

Part of our mission in this space means ensuring that food product labeling doesn't contain false or misleading statements about safety or nutrition. This includes statements that food manufacturers make on their own initiative. But it also includes statements that may be compelled under state law.

Simply put, if a state law purports to require food labeling to include a false or misleading statement, the FDA may decide to step in.

That's why we were deeply concerned when a court recently ruled that a California law – known as Proposition 65 – may require coffee sold in California to be labeled with a cancer warning because of the presence of a chemical called acrylamide. Under Proposition 65, California requires that certain products contain cancer warnings if they will expose consumers to chemicals that California health authorities

have identified as causing cancer. But requiring a cancer warning on coffee, based on the presence of acrylamide, would be more likely to mislead consumers than to inform them.

Acrylamide can form in many foods during high-temperature cooking, such as frying, roasting and baking. Acrylamide in food forms from sugars and an amino acid that are naturally present in food. It doesn't come from food packaging or the environment. In coffee, acrylamide forms during the roasting of coffee beans. Although acrylamide at high doses has been linked to cancer in animals, and coffee contains acrylamide, current science indicates that consuming coffee poses no significant risk of cancer. This finding was reflected in a comprehensive report by the World Health Organization's International Agency for Research on Cancer.

The good news is that, based on this science, the California agency that administers Proposition 65 has proposed a regulation to exempt coffee from a Proposition 65 cancer warning.

The FDA strongly supports this proposal.

As a science-based agency, the FDA is committed to ensuring that information being presented on a food's label is accurate and not misleading. That's why today the FDA sent a letter to the California Office of Environmental Health Hazard Assessment expressing our support of this proposed regulation that would exempt coffee from a Proposition 65 cancer warning.

We've taken this position because we too have carefully reviewed the most current research on coffee and cancer and it does not support a cancer warning for coffee. In fact, as our letter to California states, such a warning could mislead consumers to believe that drinking coffee could be dangerous to their health when it actually could provide health benefits. Misleading labeling on food violates the Federal Food, Drug, and Cosmetic Act. No state law can require food to bear a warning that violates federal law.

Strong and consistent evidence shows that in healthy adults moderate coffee consumption is not associated with an increased risk of major chronic diseases, such as cancer, or premature death, and some evidence suggests that coffee consumption may decrease the risk of certain cancers. To this end, current dietary guidelines published by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture state that moderate coffee consumption (three to five cups a day or up to 400 mg/day of caffeine) can be incorporated into healthy eating patterns.

This is not the first time the FDA has expressed concerns about Proposition 65 warnings based on the presence of acrylamide in foods. The FDA previously wrote to California stating our concerns about acrylamide warnings for foods because such warnings may mislead consumers about the risks posed by foods containing acrylamide and encourage consumers to alter their diets in ways that may not benefit their health. A prime example is whole grain foods. We recognize that some of these products may contain acrylamide. But we also know that consumption of whole grains

is beneficial for health and nutrition. Labeling whole grain foods with a cancer warning may cause American consumers to avoid foods that would have a benefit to their health, including avoiding foods that may reduce cancer risks.

The FDA has undertaken a number of activities on acrylamide since the discovery of acrylamide in foods in 2002, including performing toxicology research, conducting food surveys and exposure assessments and issuing [guidance for industry on mitigating the formation of acrylamide during food production](#) ([/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm374524.htm](#)). Given the widespread presence of acrylamide in foods, it isn't feasible to completely eliminate acrylamide exposure.

Removing any one or two foods from your diet would not have a significant effect on overall exposure to acrylamide. This is why the FDA's best advice is that consumers adopt a healthy diet, consistent with the [Dietary Guidelines for Americans \(2015-2020\)](#) (<http://health.gov/dietaryguidelines/2015/>). It emphasizes fruits, vegetables, whole grains, and fat-free or low-fat milk and milk products; includes lean meats, poultry, fish, beans, eggs, and nuts; healthy oils, and limits saturated fats, trans fats, sodium, and added sugars.

Assuring that consumers have access to transparent science-based nutrition information is a pivotal element of the FDA's public health mission. These goals are encompassed in the multi-year [Nutrition Innovation Strategy](#) ([/NewsEvents/Speeches/ucm603057.htm](#)) that we announced in March. This Innovation Strategy involves a series of synergistic actions intended to modernize the FDA's approach to nutrition, help reduce the burden of chronic disease that stems from poor nutrition, including obesity, diabetes, heart disease and a variety of cancers, and to remove barriers to industry innovation.

In line with our Nutrition Innovation Strategy, we strongly support exempting coffee from a cancer warning. The scientific community has conducted a substantial amount of research on the issue of whether coffee causes cancer, and the totality of that research has found inadequate evidence to establish that coffee causes cancer and suggests that coffee may even reduce the risk of some cancers.

We're dedicated to providing science-based information to consumers in an effort to benefit health and nutrition. And we remain committed to ensuring product labeling provides the most factual, easy-to-understand information needed to inform diet selections.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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