Proposition 65 Update



FRESNO VISALIA BAKERSFIELD LOS ANGELES SACRAMENTO





Proposition 65 Origins

Proposition 65 originated as an initiative approved by the people of California in 1986 to require businesses to provide clear and reasonable warning before exposing people to certain chemicals that exceed certain thresholds.

CALIFORNIA PROPOSITION 65 WARNING

WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm. (California law requires this warning to be given to customers in the State of California.)

The Operative Language

- Section 25249.6 California Health and Safety:
- No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual. Except as provided in Section 25249.10.

The Prop 65 List of Chemicals

Broad Range of Chemicals (over 850)

Includes a Number of Common Chemicals

 Includes chemicals that are commonly found in food and beverages

Interesting Prop 65 Chemicals

- Cigarette Smoke
- Diesel Fumes
- Saw Dust
- Sulphur Dioxide
- Ethyl Alcohol
- Round Up

What's Hot with Other Products

- Di(2-ethylhexyl)phthalate ("DEHP") in Plastics-Tools, Vinyl Clothes, Purses
- DEHP in eyewear
- Tris in furniture
- Lead in Various Types of Food and Supplements
- Coconut oil diethanolamine in cosmetics, soaps, shampoo
- BPA in Plastic Items
- Carbon Monoxide in Combustible Items

How Chemicals are Added

- Chemicals may be added to the Prop 65 list by.....
 - Chemicals identified by WHO.
 - Chemicals identified by CA's "qualified experts."
 - Chemicals identified by "authoritative bodies."
 - Chemicals that a state or federal government agency requires to be labeled as causing cancer or birth defects.

Limitations

- o Companies Under 10 Employees.
- Federal Preemption
- Occupational Hazards Covered by the <u>Hazcomm</u> Standard
- Prescription Drug Presumption
- 12 month period after the chemical is initially listed before a violation could occur

Exposure, means:

• 25102(i) "Exposure" means to cause to <u>ingest</u>, <u>inhale</u>, <u>contact via body surfaces of otherwise</u> <u>come into contact with a listed chemical</u>.

• Three classes of exposure: as a consumer, as an employee, or in the environment. Each will impact the scope of the required warnings.

"Knowingly" means knowledge that the discharge is occurring NOT that it is unlawful

• 25102(n) "Knowingly" refers only to knowledge of the fact that a discharge of, release of, or exposure to a chemical listed pursuant to Section 25249.8(a) of the Act is occurring. No knowledge that the discharge, release or exposure is unlawful is required.

Do You Need A Warning

- How do you know whether you need a warning?
- Need to know what is in your product
- Need to know whether under the dosage situation:
 - You exceed the NOEL or in the case of reproductive effects the MADL.
 - o If there is no MADL or NSRL you need an expert to provide you with that opinion.
 - What if you are over?
 - ➤ Provide the appropriate warning
 - ➤ Or if you can find out what is causing the levels and reduce them, change or eliminate the ingredients.

No Warning Requirement if the Levels are less than the NSRL and NOEL

- (C) An exposure which... poses No Significant Risk [NSRL] assuming lifetime exposure at the level in question for substances known to the state to cause cancer, (1 in 100,000 cancer risk)
- and that the exposure will have No Observable Effect [NOEL] assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity....based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing...The MADL Max Allowable Dose Level is determined from the NOEL.
- In any action brought to enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant.

"Scientifically valid testing according to generally accepted principles"

 A chemical is known to the state to cause cancer or reproductive toxicityif in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity,

Enforcement

- Enforcement by the Attorney General
 - OAny district attorney.
 - OAny city attorney for cities whose populations exceed 750,000

Bounty Hunter Provisions

• Of particular interest for manufactures distributors and retailers the Proposition contains a bounty hunter provision that has made it a fertile area for legitimate environmental interests and less altruistic Plaintiff's Counsel.

Managing a Sixty Day Notice

60 DAY NOTICE OF VIOLATION

SENT IN COMPLIANCE WITH CALIFORNIA HEALTH & SAFETY CODE \$25249.7(d)

DATE: December 22, 2017

To: President or CEO - Ace Hardware Corporation

President or CEO - ConservCo

President or CEO - ConservCo Water Conservation Products, LLC California Attorney General's Office;

District Attorney's Office for 58 counties;

City Attorney's for San Francisco, San Diego, San Jose, and Los Angeles.

From: Mr. Kingpun Cheng

My name is Kingpun Cheng. I am a citizen of the State of California acting in the interest of the general public. I seek to promote awareness of exposures to toxic chemicals in products sold in California and, if possible, to improve human health by reducing hazardous substances contained in such items. This Notice is provided to the parties listed above pursuant to California Health & Safety Code §25249, 6 et seq. ("Proposition 65"). The violations covered by this Notice consists of the product exposures, routes of exposures, and types of harm potentially resulting from exposure to the toxic chemical ("listed chemical") identified below as follows

> Product Exposure: See Section VII. Exhibit A Listed Chemical: Lead and Lead Compounds

Routes of Exposure: Dermal absorption, Ingestion, Inhalation

Carcinogen, Causes Birth Defects and Other Reproductive Harm

II. NATURE OF ALLEGED VIOLATION (PRODUCT EXPOSURE)

The specific type of product that is causing consumer exposures in violation of Proposition 65, and that is covered by this Notice, is listed under "Product Category/Type" in Exhibit A in Section VII below. All products within the type covered by this Notice shall be referred to hereinafter as the "products."

The sale of these products in the state of California dating at least as far back as November 10, 2017 are subject to this notice. As a result, exposures to the listed chemical from the use of the products have been occurring without clear and reasonable warnings as required by Proposition 65. Without proper warnings regarding the toxic effects of exposures to the listed chemical, resulting from contact with the products, California citizen lack the information necessary to make informed decisions on whether and how to eliminate (or reduce) the risk of exposure to the toxic chemical from the reasonably foreseeable use of the products.

California citizens, including children, through the act of buying, acquiring or utilizing the products, are expo the listed chemical in homes, workplaces, cars, and places throughout California where these products are used. By way of example but not limitation, exposures occur when California citizens use, install, attach, fix, adjust, connect detach, move, store or otherwise handle these products, the listed chemical transfers onto the hands through routine touching of the parts and portions of the products containing readily available surface amounts of the listed chemical and is subsequently absorbed through the skin or ingested via inhalation, hand-to-mouth behavior, hand-to-food-to-mouth behavior, or through hand-to-eigarette-to-lung behavior. Exposure may continue to occur for a significant period after the initial contact. These activities cause California citizens to be exposed directly through migration of the listed chemical from the products. California citizens likely to be exposed are men, women, and children. These violations and threatened violations pertain to Proposition 65 chemicals that are listed as carcinogens and as reproductive toxins

Significant Procedural Aspects of Prop 65

- Sixty Day Notice
 - Certificate of Merit
 - Notice to County Prosecutors/State
 - Settlement Approval by Court and AG

60 Day Notice

• Sixty Day Notice Provides Government Agencies the opportunity to decide whether to prosecute the case.

• The second purpose is to give the defendant an opportunity to cure the violation.

 Insufficient content may bar a case from proceeding.

Certificate of Merit is Required

- Expert declaration that the case is meritorious is required.
- If the court determines after trial that there was no actual or threatened exposure to a listed chemical, the court on motion or Sua Sponte can review the foundation for executing the certificate and issue sanctions
- On September 14, 2017, the Legislature amended the certificate of merit provisions and sent <u>AB 1583</u> to Governor Brown for signature in October . AB 1583 accomplished two things:

AB 1583

- Require the Attorney General to send a letter to the private enforcer and the recipients of the 60-day notice when the Attorney General has reviewed the certificate of merit and determined that there is no merit to an action;
- Make the basis for the certificate of merit discoverable in litigation, to the extent that the information is relevant to the subject matter of the action and not subject to the attorney-client privilege, the attorney work product privilege, or any other legal privilege.

Citizen Suit

- Under Prop 65 Citizen Plaintiff obtains the right to proceed in the "Public Interest".
- It also obtains the right to seek penalties. 75% of which would go to the state and 25% to Plaintiff.

Defenses

- 1. Preemption
- 2. Safe Harbor Levels
- 3. Naturally Occurring (food only)

Settlement Issues

- Most cases settle.
 - Business Decision
 - ➤ Litigation Costs vs. Settlement Costs
- Provisions
 - Labeling.
 - ➤ With food, is this an option?
 - **▼** Usually of Existing Inventory
- Reformulation
- Out of Court Settlements
 - Res Judicata
- Scope of Releases
 - Attorney General Letter regarding Settlement in the Public Interest

Defenses: Safe Harbor Intake Levels

- Acrylamide: 20 μg / day
- Cadmium: 4.1 μg / day
- Lead: 0.5 μg / day
- Ethylene oxide: 2 μg / day
- Formaldehyde: 40 μg / day
- 4-Methylimidazole (4-MEI): 29 μg / day [effective Feb. 8, 2012]
- More: http://oehha.ca.gov/prop65/getNSRLs.html

How Do You Determine the Threshold

- Hire an expert
- Quantification of the chemical concentration of a listed chemical for the exposure in question (level in question);
- Multiply the level in question by the reasonably anticipated rate of an exposure for an individual to the food;
- The rate of exposure must be based on the pattern and duration of exposure that is relevant to the reproductive or carcinogenic effect which formed the basis for listing the chemical as covering reproductive toxicity.

Many "Safe Harbor" Numbers are set by Settlement

- As indicated because of the way consent judgment are negotiated among parties and then court approved many safe harbor numbers are set by litigants and their experts as opposed to the government. This can be frustrating to parties that did not participate in the process but are now burdened with a particular threshold.
- May be difficult to find because they are buried in old judgments.

Warning Requirements

↑ WARNING

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 or birth defects or other reproductive harm. For more information, go to www.p65Warnings.ca.gov/furniture.

Clear and Reasonable

- A warning is considered "clear and reasonable" within the meaning of Section 25249.6 of the Act if it complies with all of the applicable requirements of the article.
- The text of a warning must include the name(s) of the listed chemicals in the consumer product or affected area for which the warning is provided. If a warning for more than one endpoint is required, the name of all the chemicals for each endpoint must be included in the warning. The exception is where a listed chemical is known to cause both cancer and reproductive toxicity and this information has been included in the warning.

Safe Harbor Warnings

- In order to avoid confusion the OEHHA issued regulations that include the so-called safe harbor warnings that if used are presumptively sufficient.
- Implicit Safe Harbor Language (and safe harbor exposure levels) are also created by the language used in consent decrees.

Despite the Safe Harbor Other Warnings are allowed

• Nothing in this section shall be construed to preclude a person from providing warnings other than those specified in this article that satisfy the requirements of this article, or to require that warnings be provided separately to each exposed individual.

Summary Of New Regulations

- In summary, there is new safe harbor language, a new website for consumers, and attempts to clarify liability as between manufacturers and retailers.
- The new regulations go into effect on August 30, 2018, new labels can however be used before that time.
- The language required by Consent Judgments is considered within safe harbor.

New Regulations Continued

- The new labels contain language that requires the identification of at least one of the Proposition 65 chemicals in the product. The language for each of the types of warnings (i.e. environmental vs. product) has changed.
- The emphasis is for liability to the manufacturer; along with additional duties toward vendors.
- There is new web Proposition 65 site sponsored by OEHHA.
- There are new symbols required on the safe harbor labels.

Manufacturers/Retailers' Responsibility

- Manufacturer/Retail Seller Responsibilities
- Product manufacturers have primary responsibility for warning.
 - O Manufacturer can label product *or p*rovide notice to distributor/importer/retail seller that a product may cause an exposure to a listed chemical.
 - Provide warning signs, materials (unless they make other arrangements via contract).
 - Retail sellers confirm receipt of notice
 - Act as "pass-through" for warning
- Provide non-English language warnings in certain situations.

Recent Changes to Warning Requirements

- Overview
- Clarifies responsibilities to provide warnings
 - Retains "safe harbor" approach for warnings to provide flexibility for businesses. Includes changes to warning methods and content
 - Provides for more specificity and clarity in warnings
 - Added "tailored" warnings for specific kinds of exposure.
 - × Examples: dental care, furniture, diesel engines, automobiles, recreational vessels, amusement parks.

Consumer/Environmental Exposures

- Consumer product exposure warnings must be displayed on a label, labeling, or sign in such a way that the information is "likely to be read and understood by an ordinary individual." In other words, the warnings must be conspicuous when compared to other information contained on the same label, etc.
- Environmental exposure warnings are also required to be displayed in such a manner that a typical citizen would be likely to read and understand the warnings.
- The warning content may contain information which identifies the source of the exposure or provides information on how to avoid or reduce exposure to the identified chemical(s). Any such supplemental information is not a substitute for the warning content.

New Warning Required

- This is a new section which is derived from section 25603. This section provides very specific requirements on how warnings are transmitted (communicated) to the consumer. <u>Please pay particular attention to font size requirements and other precise obligations.</u>
- Warnings are required to meet Section 25603 requirements and be provided utilizing one or more of the following methods:
 - A product-specific warning, on a posted sign, shelf tag or shelf sign, is required for the consumer product at each point of display.
 - A product-specific warning provided via any electronic devise or process which automatically provides the warning to the purchaser prior to or during the purchase of the consumer product.
- Label in compliance with Section 25603(a).
- An on-product warning in type size no smaller than the largest type size used for other consumer information on the product with a minimize 6-point type
- For internet purposes either a hyperlink using the world "WARNING" on the product display page or a warning compliant with Section 25603(a).
- For catalog purchases, the warning must be provided in a manner which clearly associates the warning with the item being purchased. Online, catalog and on-product warnings may use the same content.
- If warning is in a language other than English, an English translation must also be provided.

New Label Requirements

- Warnings are compliant only if they use one or more of the transmissions methods identified in 25602 and includes ALL of the following elements:
- O A symbol consisting of a black exclamation point in a yellow equilateral triangle with a bold black outline. Where the sign, label or shelf tag for the product is not printed using the color yellow, the symbol may be printed in black and white. The symbol shall be placed to the left of the text of the warning, in a size no smaller than the height of the word "WARNING."



New Requirements. Cancer Cont.

 The world "WARNING" in all capital letters and bold print; and:

The following sentence must be used for exposures to listed carcinogens:"

WARNING

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. For more information go to www.P65Warnings.ca.gov."

New Requirements. Reproductive Harm Cont.

• The following sentence must be used for exposures to listed reproductive toxicants:"

WARNING

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 birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov."

Warning for Cancer and Reproductive

• The following sentence must be used for exposures <u>to both</u> listed carcinogens and reproductive toxicants: "

WARNING

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."

Label Requirements

- If the warning addresses a single chemical, the worlds "chemicals including" can be deleted from the above mandatory sentences.
- (b)An on-product warning should use all of the following elements:
- (1) The symbol requirements in subsection (a) (1)
- (2) The word "WARNING" in all capital letters and in bold print.
- (A) The warning for consumer products which cause exposure to a listed carcinogens must include the wording "Cancer www.P65Warnings.ca.gov."

Cont.Requirements

- Warning symbol
- Phase In:
- There was a Two-year phase-in period.
- Effective date of regulation: August 30, 2018.
- Consumer products manufactured prior to the effective date will not require new warnings if they meet existing safe harbor requirements.
- Court-approved warnings expressly recognized and considered "clear and reasonable" for parties to litigation.
- Tailored Warnings; in addition to the specific warnings listed above, the code has modified the warnings for the following categories:

Tailored Warnings

- Environmental Exposure
- Occupational Exposure
- Specific Product, Chemical and Area Exposure Warnings
- Food
- Alcoholic Beverages
- Food and Non-Alcoholic Beverages
- Prescription Drug Exposure and Emergency Medical or Dental Care Exposure
- Dental Care
- Raw Wood Products
- Furniture Products
- Diesel Engines
- Vehicles
- Recreational Vessels
- Enclosed Parking Facilities
- Amusement Parks
- Petroleum Products
- Service Station and Vehicle Repair
- Designated Smoking Areas

Examples of Listed Chemicals Relevant to Food Products

- **Acrylamide-** French fries, coffee, popcorn, cereals
- ➤ **PhiP-** cooked or grilled chicken
- ➤ Phthalates- handbags, shoes, exercise equipment, crafts, tools
- **➤ Cadmium** jewelry, fertilizer, artist paint
- ➤ **Lead** handbags, shoes, jewelry, tools, juice, honey, supplements, photo albums, paints
- **▼ Arsenic** water filter systems, supplements

Naturally Occurring Exemption

ARTICLE 5. Extent of Exposure

§ 25501. Exposure to a Naturally Occurring Chemical in a Food

- (a) Human consumption of a food shall not constitute an "exposure" for purposes of Section 25249.6 of the Act to a listed chemical in the food to the extent that the person responsible for the exposure can show that the chemical is naturally occurring in the food.
- (b) A person otherwise responsible for an exposure to a listed chemical in a consumer product, other than food, does not "expose" an individual within the meaning of Section 25249.6 of the Act to the extent that the person can show that the chemical was a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product. Where a consumer product contains a listed chemical, and the source of the chemical is in part from a naturally occurring chemical in food and in part from other sources, "exposure" can only occur as to that portion of the chemical from other sources.
- NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Section 25249.6, Health and Safety Code.

Defenses: Naturally Occurring

- People ex rel. Edmund G. Brown Jr. v. Tri-Union Seafoods, LLC, 171 Cal. App. 4th 1549 (2009)
- Court found that the mercury that was in tuna was naturally occurring, although the Court did leave the door open for additional evidence otherwise.

Defenses: Naturally Occurring

- No duty relative to the exposure if caused by chemicals that naturally occur in the food product.
- Is a defense only to the extent you can prove that the chemical is naturally occurring by expert testimony- there can no man-made component.
- May require extensive research going back to the place where it is grown.
- Expensive and difficult to prove.

Environmental Law Foundation v. Beech-Nut et al (Alameda Superior Court 2013)

- Recent case with respect to food and fruit juice with alleged lead levels
- Court found:
 - No Federal Preemption
 - Insufficient Proof that the lead was Naturally Occurring
 - Did find that the Exposure Assessment was done correctly and allowed the use of average dosages over time, rather than looking at acute exposure

Final Suggestions

- Clients need to know what's in their product
- Need to know whether you exceed the Safe Harbor or Settlement thresholds
- If Client can need to contractually place the onus on Client's suppliers to meet the regulations
- Insurance for Proposition 65 if possible
- Do as much negotiating during can do the sixty notice period in the Proposition 65 cases
- Make business decision as to how to proceed
- You need to have an attorney and expert on call to handle these issues

Contact Information

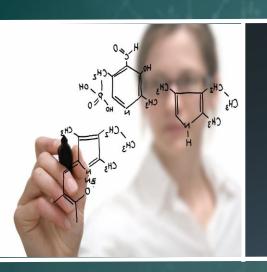


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Determining Compliance for Proposition 65

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Proposition 65 Compliance Strategies

- Option 1: WARN. However...
 - New 2018 warnings requirements
 - Not reasonable in some situations
 - Branding issues/competitor products
 - Some retailers do not want Prop 65 labeled products
 - Over-warning issue
 - Unlikely to be served with a 60-day notice but ...
 - Requires a well-managed labeling program
 - Be ready for customers' inquires/questions, aggressive public interest groups
 - Be ready for plaintiffs to look for inaccurate/"improper" 2018 labels



Proposition 65 Compliance Strategies

- Option 2: Demonstrate exposure is below Safe Harbor Level. However...
 - Requires that you know what's in your products
 - Requires conducting technical assessment of your products
 - In-house product testing from each supplier
 - Documentation program
 - Internal checks/auditing off-the-shelf testing
 - You may still be served with a 60-day notice but you will be prepared
 - Often technical exposure assessments are used in settlement negotiations
 - Regardless of the potential for Prop 65 litigation, some just want to know the answer and have the documentation.

What is a Safe Harbor Level?

- NOT an easily understood value
- What it is NOT:
 - Not the concentration of a chemical in product
 - Not the % of chemical in a product
 - Not the same level as other U.S. or international product requirements
- What it IS:
 - Dose or exposure (in µg/day) from typical use of product
 - Lead: 0.5 µg/day;
 - Diethylhexyl phthalate (DEHP): 410 μg/day
 - Formaldehyde: 40 µg/day
- For a few chemicals (e.g., lead and phthalates), Prop 65 settlements have morphed into content requirements for ease of implementation

Safe Harbor Levels

- For carcinogens no significant risk level (NSRL)
 - E.g. acrylamide and formaldehyde
- For reproductive toxicants maximum allowable dose level (MADL)
 - E.g. lead and DEHP
- Not available for all listed chemicals

Routes of Exposure

- Inhalation, ingestion and dermal routes
- Route(s) depend on the chemical and use scenario of product
- e.g.
 - Formaldehyde emissions from wood products Inhalation
 - Lead from brass products Incidental ingestion from hand to mouth contact
 - Phthalates from PVC cords Dermal and Ingestion
 - Acrylamide from food products Ingestion only

Exposure Assessment

- Conduct exposure simulations in a representative use scenario!!!
 - Chemicals used in product ≠ chemicals dislodged from product (exposure)
- Different products require different exposure scenarios based on their handling in real-life
 - Determines how to conduct product testing



Testing Methods

- Product-use simulation
 - Handle/use product wipe skin area in contact with product
 - E.g. lead in brass products or DEHP in PVC cords
- Emissions testing
 - To understand concentration in a living space
 - E.g. formaldehyde from wood products
- Leaching
 - To understand chemical unloading when mouthed
 - E.g. phthalates in children's toys
- Total content testing typically not representative of exposure for these scenarios!!!



Case Study: DEHP in PVC Tool Handle Cover

- Exposure scenario
 - Typical use by an adult
 - Anticipated exposure during use of tool
 - Estimated contact duration will depend on tool but let's assume 30 minutes per day
- Exposure assessment
 - Volunteer handles the tool, e.g. clasps, in anticipated manner for 30 minutes
 - Collect wipe samples from hand contact area after this duration
 - Analyze for DEHP and estimate ingestion and dermal exposure in μg/day for comparison to MADL of 410 μg/day

Case Study: Formaldehyde in Laminate Flooring

- Exposure scenario
 - Formaldehyde emissions into indoor air from laminate flooring
 - Estimated duration of exposure 12 hours a day spent at home
- Exposure assessment
 - Evaluate emissions from flooring in a chamber
 - Estimate indoor air concentrations from total flooring coverage and other necessary parameters
 - Calculate lifetime inhalation daily dose (formaldehyde is listed as a carcinogen)
 - Compare to NSRL of 40 μg/day

What Should You Do?

- Identify your at-risk products
 - Understand if Prop 65 chemicals are present
 - Is Prop 65 chemical easily identified (i.e., brass)?
- Evaluate potential exposure risk from use of your products
- Consider business and legal risks
- Identify compliance strategy for different products
 - Label, Or
 - Demonstrate exposure is below Safe Harbor Level
 - Consider applying for an SUD

Safe Use Determination (SUD)

"...a written statement issued by OEHHA, which interprets and applies Proposition 65 and its implementing regulations to a specific set of facts in response to a request by a business or a trade group. Requests for SUDs seek OEHHA's determination whether an exposure or discharge of a listed chemical resulting from specific business actions or the average use of a specific product is subject to the warning requirement or discharge prohibition."

- Work with OEHHA to develop an SUD for your product
- Must be prior to receiving any notice of violation (NOV)
- Many businesses/trade groups are choosing this route



Thank you – QUESTIONS?

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