Monet Vela  
Office of Environmental Health Hazard Assessment  
P. O. Box 4010  
1001 I Street  
Sacramento, CA 95812-4010

_Sent Electronically to:_ P65Public.comments@oehha.ca.gov

**SUBJECT: Prop 65 Warning Regulation**

Dear Ms. Vela:

We are writing on behalf of the members of the Association of Global Automakers, Inc.\(^1\) (Global Automakers) and the Alliance of Automobile Manufacturers\(^2\) (Auto Alliance), which include nearly every company selling new vehicles in the United States (U.S.). We appreciate the opportunity to provide the following comments\(^3\) on the pre-regulatory proposal for the Proposition 65 (Prop 65)\(^4\) warning requirements.

**OVERVIEW**

In the pre-regulatory Initial Statement of Reasons (ISOR) and accompanying pre-regulatory (or draft) proposal (pre-proposal) for the Prop 65 warning requirements, the California Office of Environmental Health Hazard Assessment (OEHHA) stated that it believes changes to Prop 65 are necessary to:

- Provide more useful information to the public;
- Offer businesses greater flexibility and certainty; and

\(^1\) Global Automakers’ members include Aston Martin, Ferrari, Honda, Hyundai, Isuzu, Kia, Maserati, McLaren, Nissan, Subaru, Suzuki, and Toyota. Please visit [www.globalautomakers.org](http://www.globalautomakers.org) for further information.

\(^2\) Auto Alliance members include BMW, Chrysler, Ford, General Motors, Jaguar Land Rover, Mazda, Mercedes-Benz, Mitsubishi, Porsche, Toyota, Volkswagen, and Volvo. See [www.autoalliance.org](http://www/autoalliance.org) for further information.

\(^3\) In addition to these written comments submitted jointly by Global Automakers and the Auto Alliance, we adopt the comments submitted by the California Chamber of Commerce by reference.

• Take advantage of the tremendous growth and innovation in technology since the
Prop 65 warning requirements were implemented in 1986.

In addition to the reasons cited above, OEHHA expressed concern at the April 14, 2014
Pre-Regulatory Workshop that:

• The current generic “safe harbor” warning does not provide adequate information
to the public;
• Businesses are using the hazard warnings without really determining if there is a
potential exposure, and therefore the warnings have become meaningless; and
• There is too much flexibility in the current system.

While we appreciate OEHHA’s attempt to make the warning requirements more
meaningful to the public, OEHHA should give further consideration to the very real
differences between the types of products that it is trying to regulate, and the complexity
of the requirements that would be imposed.

Complex durable goods, such as airplanes, boats, and automobiles do not lend themselves
practically to the types of warning label requirements that OEHHA is considering. When
considering issues unique to complex durable goods, these potential changes are
unreasonably burdensome. Specific concerns that represent an unreasonable burden
include: applicability to information requirements, replacement parts, lead time
(compliance timing), confidentiality, costs, and duplicative mandates. We urge OEHHA
to garner a better understanding of the universe of products it is trying to regulate, to
recognize the very real differences between complex durable goods and other products,
and to work closely with the automotive sector to design and develop a plan that is
workable, meaningful, and cost effective.

In addition to concerns relating to complex durable goods, we also find the proposal to be
so vague and unclear that it presents an unworkable framework that will be impractical to
implement. Specifically, we have concerns regarding many of the definitions and terms,
the use of the GHS pictogram, reporting requirements, new labeling wording, and the
procedure used in selection of the 12 named chemicals.

Despite being drafted with the best of intentions, the Prop 65 reform pre-proposal fails to
provide a workable framework, fails to address many of the manufacturing realities of
complex durable products, and fails to achieve its goal to improve the current system.
OEHHA should reevaluate and revise the pre-proposal and should allow for another
round of public comment before proceeding with the regulatory process. We have
outlined our specific concerns below.
CONCERNS

THE PROP 65 REFORM PROPOSAL IS UNREASONABLY BURDENSOME FOR COMPLEX DURABLE GOODS MANUFACTURERS

Complex Durable Goods

OEHHA’s drafted Prop 65 changes will be unreasonably burdensome for manufacturers of complex durable goods. The proposed revisions will be impractical, unworkable, and cost prohibitive to implement, particularly for complex durable goods such as automobiles. Issues with the pre-proposal arise with consideration of the availability of information in the supply chain, timing proposed in the draft, and impacts on consumers, confidentiality, service parts, and costs.

Complex durable goods, as the name implies, are products that are assembled from hundreds, or even thousands, of individual components. The average automobile is a complex web of systems and networks, containing more than 3,000 unique components from thousands of suppliers around the world, and the supplier network for these components can be as deep as six to seven tiers. The global nature of the supply chain greatly complicates information-gathering capabilities.

Automobile manufacturers have complied with the current Prop 65 warning requirements by providing a single, general warning notification in the vehicle’s owner’s manual. The reason for this is twofold. First, there are a multitude of Prop 65 chemicals present in numerous components, and it is more expeditious to provide a single notification. Second, there are already many different labels within a vehicle, providing manufacturing, fuel type, tire pressure, safety systems, other environmental information, etc. Therefore, the single warning in the owner’s manual helps to address concerns with an overabundance of labeling on the vehicle. Furthermore, OEHHA’s pre-proposal is not clear as to whether this single label will still comply going forward, how to generate the warning notification, when multiple chemicals must be addressed, or what exposure threshold levels will be used to determine when a notification is necessary; these concerns are addressed further below.

Recommendation: OEHHA should not require specific labels for complex durable goods and should clarify that a single, general notification, such as a warning in the owner’s manual, continues to comply with the Prop 65 warning requirements.

5 Other characteristics of complex durable goods include an intended useful life of five or more years and the product is not typically consumed, destroyed, or discarded after a single use.
**Information Requirements**

OEHHA’s pre-proposal would involve an unprecedented amount of communication between manufacturers and suppliers and require manufacturers to submit information about chemical concentrations and potential exposure pathways for all chemicals in all components of an automobile. This expectation is both unrealistic and unworkable.

**Information Collection**

The automotive sector has worked diligently to ensure that we use the safest technologies available in our products. We have developed both the International Material Database System (IMDS) and the Global Automotive Declarable Substance List (GADSL) to help avoid using substances that have been regulated based on health or environmental concerns.

The automotive industry utilizes the IMDS as the global standard for reporting material content in the automotive industry to gather information about the content of components for compliance with European regulations. It has taken 15 years to populate the IMDS with the information it currently contains, resulting in over one million records on finished parts today. Those finished parts are comprised of less than a dozen to hundreds of sub-components from as many sub-suppliers around the world. However, IMDS does not provide information about potential exposure pathways and, for many of the chemicals, provides a *de minimis* standard of 0.1% at which chemicals do not have to be disclosed. Therefore, while the automotive industry does have a system in place to investigate the chemical content of the thousands of parts in the vehicle, OEHHA’s requirements go far beyond the IMDS’s resources and capabilities. It would certainly take another 15 years or longer to gather additional information about precise concentrations and potential exposure pathways.

Furthermore, even if the chemical content information is available in IMDS, it is not clear the Original Equipment Manufacturers (OEMs) could share that information. Under the current practice, OEMs and suppliers have confidentiality agreements. Therefore, OEMs can use information in IMDS to determine compliance, but depending on what is ultimately required, OEMs may not be able to share supplier IMDS data. The agreement to protect proprietary formulations and/or concentration data has been fundamental in populating the information within IMDS.

GADSL provides a definitive list of substances that are regulated by governments – both domestic and international. Its intent is to ensure efficient management of regulatory requirements along a complex supply chain. GADSL ultimately informs many of the
substances that must be declared in IMDS. GADSL includes information on regulated substances relevant to parts and materials supplied throughout the automotive value chain, from production to the end-of-life phase. GADSL also includes substances that are expected to be present in a material or part that remains in the vehicle or part at point of sale. The listings in GADSL are based on the threshold levels routinely assigned at 0.1%.

The automotive sector has made significant investments in these data systems so that the sector could be forward thinking, could make informed environmental choices, and could be in compliance with regulations impacting our products. Although significant resources have been devoted to development of IMDS and GADSL, neither database provides the type of “safe harbor” information that the pre-proposal calls for. For the over 800 Prop 65-listed chemicals, only approximately 300 have “safe harbor” levels, and those safe harbor levels are expressed as exposure levels (No Significant Risk Level or NSRL (µg/day)), not percent-by-weight. Therefore, neither the IMDS nor the GADSL system would help determine our duty to comply. Further, there is no data source for the automotive sector to use to access information that would allow us to determine if we were below the safe harbor level and therefore not required to label. For the over 500 chemicals with no safe harbor level, we would automatically be required to test for exposure potential once we determined that any one of them were present in any individual component.

As an example, Table 1 below indicates the complexity of the various systems in an automobile. If OEHHA’s pre-proposal were put in place, the manufacturer would need to test each of these components to determine the presence of any Prop 65 chemicals, unless the supplier of the component provided that information. Even then, many OEMs sell various configurations of vehicles, for instance each with different transmissions, increasing the amount of information needed for each differing component within different transmission systems. Either way, a substantial amount of data collection and/or testing will be necessary under OEHHA’s draft proposal.

Table 1

<table>
<thead>
<tr>
<th>Example: Transmission System Components</th>
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</thead>
<tbody>
<tr>
<td>Bracket Assembly</td>
</tr>
<tr>
<td>Case</td>
</tr>
<tr>
<td>Case Cover</td>
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<tr>
<td>Differential Assembly</td>
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<tr>
<td>Drive Sprocket</td>
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<tr>
<td>Final Drive Internal Gear</td>
</tr>
<tr>
<td>Gasket</td>
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<tr>
<td>Governor Assembly Housing Input</td>
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<tr>
<td>Internal Gear</td>
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<tr>
<td>Input Planetary Gear Set</td>
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<tr>
<td>Internal Gear</td>
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<tr>
<td>Manual Detent Lever</td>
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<tr>
<td>Manual Shaft Low and Reverse Clutch</td>
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<tr>
<td>Manual Valve Plate Assembly</td>
</tr>
<tr>
<td>Reaction Planetary Gear Set</td>
</tr>
<tr>
<td>Roller Clutch</td>
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<tr>
<td>Spacer Plate</td>
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<tr>
<td>Speedometer Drive Gear</td>
</tr>
<tr>
<td>Parking Lock Pawl</td>
</tr>
<tr>
<td>Throttle Lever</td>
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<tr>
<td>Torque Converter Reaction</td>
</tr>
</tbody>
</table>

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6 http://www.carparts.com/transmission.htm#Transmission%20Components
Even if the supplier did provide information regarding the presence of a chemical, the manufacturer would then be required to ascertain the chemical’s concentration and potential for exposure. It is not clear that OEHHA has considered or even determined what those testing costs might be. In OEHHA’s own words, “determining anticipated levels of exposure to listed chemicals can be very complex.”7

When the global supply chain cannot respond to the level of detail being suggested, the duty to develop that information will fall to the automobile manufacturer. For each of the components used in the automobile, the manufacturer will be required to determine (1) if any of the Prop 65-listed chemicals are present; (2) if the level of the chemical is above OEHHA’s “safe harbor” levels if one exists; (3) if there is any potential exposure to the chemical under not only consumer use conditions but also workplace situations; and (4) what actions could be taken to mitigate concerns.

**Exposure Levels**

The pre-proposal suggests that there is a need for the development of information on actions to minimize or eliminate exposure. OEHHA is requesting information on exposure that it has refrained from using, as signaled by the fact that OEHHA has not established safe harbor levels8 for more than half of the Prop 65-listed chemicals. This type of information is beyond the scope of traditional toxicity testing. The pre-proposal suggests that for each chemical in each component, the manufacturer would be required to perform some type of alternatives assessment.

The pre-proposal also seems to create a responsibility on the manufacturer to continually monitor and update the information that the manufacturer has provided to OEHHA. For example, if a new exposure study is developed or if new information on risk mitigation becomes available, is OEHHA suggesting that manufacturers must set up a system to monitor new developments?

In addition to the uncertainty that these new warnings would create, OEHHA is creating the opportunity for “dueling exposure determinations.” Given that the current Prop 65 relies on consumers and competitors to turn in potential violators of Prop 65 requirements, it is inevitable that groups will perform their own exposure studies and challenge the studies and determinations made by manufacturers. If this pre-proposal moves forward, the litigation and science challenges that could result would far exceed the current issues.

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7 http://oehha.ca.gov/prop65/background/p65plain.html
8 Safe harbor levels include No Significant Risk Levels (NSRLs) for cancer-causing chemicals and Maximum Allowable Dose Levels (MADLs) (http://www.oehha.ca.gov/prop65/getnsrls.html).
**Recommendation:** OEHHA should not require manufacturers to provide exposure information. Instead, OEHHA should set exposure thresholds for all Prop 65-listed chemicals. OEHHA should also provide a standard *de minimis* threshold of 0.1% by volume to clarify that products with consumer exposure levels below this threshold would not be subject to the warning requirements.

**Replacement Parts**

Ensuring that replacement parts remain available for complex durable goods is critical. Numerous unique factors interact to make the supply of replacement parts a challenge in any scenario, and the constraints that warning label changes would impose make those challenges insurmountable. An exemption for replacement parts already in inventory and for replacement parts produced to repair a vehicle as produced9 is necessary, as described below:

- Replacement parts used in vehicle repairs are available for 20 years or more after the vehicle ceases production, and are often produced early in the vehicle’s production period to create stock inventories to service the vehicle throughout its useful life.
- Complex durable goods typically are intended to last several years, even decades. Replacement parts must remain available for years, even for products that are no longer being manufactured.
- As we have seen with the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Program, it is extremely difficult, if not impossible, to determine material content for replacement parts that are no longer in production.
- Frequently replacement parts must meet specific legal requirements and/or regulatory approvals or certifications.
- With the multi-tiered, multi-faceted global supply chain inherent in the manufacture of complex durable goods, information regarding the content of replacement parts may no longer be available depending on when it was manufactured or whether the parts manufacturer is still in business.
- Often, replacement parts cannot be used interchangeably; therefore specific parts must be available to specific models.

Other organizations have recognized the concerns set forth above. For example, broad exemptions for replacement parts can be found in the End-of-Life Vehicle (ELV) regulations.

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9 In the context of “repairing a vehicle as produced,” the assumption is that the replacement part would be exempted only if the vehicle was produced prior to any changes to the Prop 65 warning requirement.
Directive allowing vehicles to be repaired as produced. The Restriction of the Use of Certain Hazardous Substances (RoHS) Directive (Article 2(3)) makes it clear that the directive does not apply to spare parts for the repair of electrical and electronic equipment put on the market before July 1, 2006, in order to ensure the availability of spare parts for equipment placed on the market before the entry into force of the substance restrictions. More recently, laws in California (SB 346, “Hazardous Materials; Motor Vehicle Brake Friction Materials,” 2010) and Washington (SB 6557, “Brake Friction Materials – Restrictions on Uses,” 2010) regarding the copper content in brake friction materials both provided exemptions for service and replacement parts in recognition of the above noted concerns.

The long shelf life of replacement parts is, itself, a practical reason for exemption, since many replacement parts that are manufactured today -- prior to the promulgation of new Prop 65 requirements -- are likely to be on service and repair shop shelves for decades.

**Recommendation:** We recommend that OEHHA provide an explicit exemption from the warning requirements for replacement parts used to repair vehicles as produced, according to the requirements in place at the time the vehicle was produced.

**Insufficient Lead Time**

The Auto Alliance and Global Automakers have serious concerns about many of the timing issues associated with the new warning requirements in the pre-proposal.

One problem is the lack of clarity regarding lead time to implement the rule. As drafted, this proposal would require manufacturers to take many new steps to implement the provisions of the rulemaking, yet the pre-proposal is silent regarding lead time. OEHHA should provide adequate lead time to implement such significant regulatory changes.

In considering what would be “adequate” lead time, it is important to understand the lengthy and complex product development cycles in the automobile industry. Because automobiles are highly complex and innovative products, their development -- from the concept-to-testing and validation-to-production phases -- takes anywhere from four to seven years. Decisions regarding vehicle design and development are made several years before manufacture, making last-minute changes or information collection regarding components all the more difficult once production decisions have been made.

In addition, some of the information that OEHHA requests, such as exposure routes, pathways of exposure, anticipated exposure levels, or information on actions to minimize or eliminate exposure, may not be available. It could take months or even years to collect,
depending on the number of impacted components containing Prop 65-listed chemicals. Furthermore, where this information has yet to be generated, testing may take several years.

Sufficient lead time prior to implementing the regulation must be provided, and flexibility must be allotted in instances where manufacturers are making good faith efforts to obtain the information but need additional time.

In addition, the pre-proposal would require a manufacturer to provide available, detailed information to OEHHA within 30 days from the time a warning is provided. Thirty days is an unrealistic and insufficient time to gather such information through a multi-tiered supply chain. Not only would a manufacturer have to send an information request through the supply chain and wait for responses, but the information would have to be analyzed and assessed prior to submittal. As noted earlier in our discussion of the supply chain, the complexity of the supply chain can result in longer time frames to collect information. If this information is not readily available, it may require a set of exposure studies that are both lengthy (taking months to years to complete) and costly to complete.

Recommendation: We recommend that OEHHA provide three years lead time to implement any new warning requirement provisions, and assuming the burdensome reporting requirement portion of the proposal is maintained, the timeframe during which one may complete reporting requirements should be expanded substantially.¹⁰

Confidentiality Issues

The 11 categories of information that would be required by OEHHA in Section 25604(a) of the pre-proposal raise a number of concerns about trade secret and confidentiality, as well as ownership of data. Loss of confidential business information is a threat for all competitive business enterprises. Disclosing the names of the specific chemicals or mixtures that allow products to perform or function as intended raises serious issues about the ability to protect proprietary information not only in the U.S. but internationally as well. Furthermore, as we noted above, OEMs can use information in IMDS to determine compliance, but due to confidentiality agreements between OEMs and suppliers, OEMs may not be able to directly share that information. The collective impact of the 11 categories of data and information that OEHHA proposed to be submitted and released to the public provides a roadmap for competitors to reverse engineer proprietary formulas and designs. Nowhere in the proposal is there a suggestion that a mechanism for protecting confidential business information is necessary. We believe this is a serious issue that must be considered and addressed.

¹⁰ A minimum of 90 days should be considered with additional flexibility in the timeframe as needed.
Cost

Considering the issues set forth above, it is clear that the changes reflected in the pre-proposal would significantly increase the cost of complying with Prop 65. New and added costs would include gathering the necessary information and generating data if and where necessary throughout the supply chain, redesigning labels, and reeducating employees. California’s Administrative Procedure Act requires state agencies to quantify and justify the costs of regulations, so we look forward to seeing a complete cost analysis in the event OEHHA decides to move forward with these regulatory changes.

Duplication

There are currently multiple federal and state regulations that provide for hazard and warning labels on consumers products. This pre-proposal would duplicate, and in some cases contradict, those established warning schemes. Duplication of federal and state regulation is an inefficient use of resources, not only for the regulated community, but for OEHHA and the State of California as well.

Automotive products have undergone extensive safety and environmental testing before they are introduced into commerce. Regulated by multiple federal and state agencies, manufacturers strive to meet or exceed agency standards to provide a safe and reliable product, balancing all of the necessary regulatory requirements. Duplicating or establishing conflicting warnings to those established by the other agencies will yield little or no consumer benefit.

U.S. Occupational Safety and Health Administration Warnings and Labels

For decades, the U.S. Occupational Safety and Health Administration (OSHA) has required comprehensive warning and labeling. These warnings have been refined to ensure that they meet the needs of an industrial or workplace setting. OSHA requires all employers to make chemical specific Material Safety Data Sheets (MSDSs) available to all employees. The MSDSs are also available to consumers. MSDSs have commonly been used for Prop 65 occupational exposure warnings, and while Prop 65 does not apply to out-of-state manufacturers with respect to occupational warnings, in practice, companies try to help their California customers by providing Prop 65 warnings in MSDSs, but not on labels. The changes suggested in the pre-proposal would make MSDS warnings insufficient for meeting the warning requirements of this draft rule. This change to Prop 65 labels could require a substantial change to chemical labeling of products in interstate commerce, requiring both the MSDS and a separate Prop 65 warning label.
It is also not clear OEHHA has explored the potential for conflict between what they are proposing and what OSHA requires. For instance, OSHA has used its authorities to establish Permissible Exposure Limits (PEL), a level at which an OSHA warning is not necessary. It is not clear whether Prop 65 warnings would be required in the workplace for chemicals that were below the PEL limits.

We also believe that the draft rules, if adopted, would need to be approved by OSHA as an amendment to California’s state plan under Section 18 of the Occupational Safety and Health Act. The previous approval by OSHA of the inclusion of Prop 65 into the state hazard communication standard would not cover these changes.

**Other Agencies’ Regulatory Requirements**

Other duplication with existing regulatory authorities may also result from the changes in the pre-proposal. The U.S. Environmental Protection Agency (EPA) has authority under the Toxic Substance Control Act (TSCA) for regulating chemicals and has been actively using that authority to regulate use conditions for chemicals and, in specific instances, to regulate chemicals in products. It is not clear what the relationship between this pre-proposal and EPA’s chemical in product determinations will be. For example, if EPA determines that a chemical and product combination is safe, will OEHHA require a warning regardless of the EPA determination? The Consumer Products Safety Commission (CPSC) likewise has authority to require warnings for consumer products and has used its authority under the Federal Hazardous Substances Act to require precautionary labels for consumer products.

In addition to federal oversight, states such as California are putting in place aggressive consumer product regulations, and it is not clear at all how the changes being suggested here have been harmonized with the requirements of California Department of Toxic Substance Control’s Safer Consumer Products (SCP) regulations. Not only is there no harmonization with the SCP program, there is an iterative process where a product could be determined to be safe under the SCP but nonetheless penalized by Prop 65, or vice-versa. The SCP program will require a large amount of resources to collect and generate data, which may be duplicative with OEHHA’s draft requirements. The SCP will likely require labeling requirements as well, which could result in the need for additional or different information requiring a separate label. We also question the utility of creating a new database for OEHHA when the Toxics Information Clearinghouse has just been created by California EPA and may be the best resource to harmonize and streamline information for the two programs.
Duplicative Labeling

Automakers are also concerned about the likelihood of multiple labels being required on products. We have worked hard to have agencies coordinate and collaborate to streamline labeling requirements and reduce the number of labels required on products. For example, the California Air Resources Board, National Highway Traffic Safety Administration, EPA, and Federal Trade Commission ultimately harmonized their regulations to require that only one window sticker would be necessary on a new vehicle at the point of sale to provide environmental, fuel economy, and alternative fuel vehicle information to the consumer. The result of this effort is a single, comprehensive label on the vehicle that provides a clear and consistent message to consumers about the vehicle’s environmental, fuel economy, and alternative fuel benefits and properties.

Recommendation: We encourage OEHHA to reconsider its draft requirements and instead opt for a streamlined and harmonized approach that will reduce the number of labels, provide important and necessary information in a clear and consistent manner and reduce the resources needed to comply with the regulatory requirements.

THE PROP 65 REFORM PRE-PROPOSAL IS VAGUE AND UNCLEAR

Definitions/Terms

Many sections in the proposed regulation use terms or provide definitions that are not clear. This vagueness will surely lead to confusion among parties attempting to comply with the regulation.

Many phrases in Section 25604 are undefined and vague. The meaning of terms such as “reasonably available information” or “information concerning actions a person can take” leave much room for interpretation and will result in unnecessary confusion. What is “reasonable?” How much information needs to be provided, and from what source?

Proposed Section 25602(f) adds the term “retail seller,” yet the responsibility of the retail seller is not clear. In this section “a retail seller includes those functions of a business involved in the sale of products, including foods, directly to consumers, even if the business or facility is primarily devoted to non-retail activities.” Further in the draft proposed regulation, Section 25606 states: “In most cases, providing clear and reasonable warnings for consumer products, including foods, is the primary responsibility of the product manufacturer, producer, distributor or packager. The retail seller is required to cooperate with the manufacturer, producer, distributor or packager of the product to
ensure that the warning is provided to the consumer prior to exposure.” What is meant by “most cases?” Where does the ultimate labeling responsibility lie?

Where the pre-proposal attempts to clarify provisions, the pre-proposal actually brings further confusion: “…failure to comply with this article shall be the primary responsibility of the manufacturer, producer, distributor or packager of the consumer product, provided that the retail seller makes reasonable efforts to post, maintain, or periodically replace the warnings provided.” What is a reasonable effort? How will the responsibility be divided among so many entities? As explained above, a complex durable good like an automobile has a vast global supply chain to enable the manufacture of 3,000 or more components existing in today’s vehicles.

Additional confusion will be created by changing the warning’s wording from “contain” to “will expose,” as in “Entering this area will expose you to a chemical known to the State of California to cause cancer.” The definition of “expose” in the regulations at 27 CCR § 25102(i) does not include potential exposure, but the warning would include potential exposure (since there is typically a low chance of actually being exposed to the listed chemical upon entry into the area). The proposed language could be very misleading.

**New Labeling Wording**

Section 25607.2 of the pre-proposal would change the current label’s wording from “This product contains a chemical known to the State of California to cause…” to “This product will expose you to a chemical [or chemicals] known to the State of California to cause cancer and birth defects or other reproductive harm...” Revising the language to “will expose” is problematic.

Relying on the wording “will expose” creates an unreasonable burden throughout the supply chain to determine whether or not there will be exposure, and therefore whether or not a label is necessary. OEHHA assumes that there will be exposure to the chemical in the product, when the chemical may be present in *de minimis* amounts and/or have limited exposure under normal use and exposure scenarios. Determining potential exposure will be resource intensive, time consuming and costly.

“Will expose” will also likely mislead the consumer. It assumes that the consumer is coming in contact with the product, when in complex durable goods, a component may be contained within the system, resulting in little to no exposure for the consumer under normal use conditions. How then will a consumer respond to a warning label that states: “This product will expose you to a chemical [or chemicals] known to the State of
California to cause cancer and birth defects or other reproductive harm?” The common sense question that they will ask is “Is this product safe?”

Use of “contains a chemical” is clearer and more representative of potential use scenarios than “will expose.” “Contains a chemical” will also provide more regulatory certainty for manufacturers and the regulators. Finally, “contains a chemical” provides more certainty and has a clearer meaning to the consumer than trying to understand what “will expose” means.

Recommendation: The Auto Alliance and Global Automakers support that the current wording should be maintained since it more accurately characterizes (and will not mislead the consumer about) the potential exposure to the chemical.

GHS Pictograms

Another area lacking clarity in the pre-proposal relates to the inclusion of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) pictograms on Prop 65 warnings. Use of these pictograms will create confusion for California consumers and undermine OEHHA’s goal to better inform citizens.

Recently, the Occupational Safety and Health Administration (OSHA) adopted new hazardous chemical labeling requirements in response to the United Nations’ GHS.11 However, even OSHA recognizes the label system’s failures. On its own website, OSHA admits the uncertainty and confusion with the GHS Label: “What does a label look like? Existing systems have labels that look different for the same product. We know that this leads to worker confusion, consumer uncertainty and the need for additional resources to maintain different systems.”12 We believe that use of the GHS pictogram on the Prop 65 warning label will lead to additional confusion and is unnecessary beyond the current wording, “WARNING.”

Currently, there is an abundance of “existing systems” and labels that will add to customer confusion. The DOT requires labels for use during the transport of dangerous goods.13 Meanwhile, employers also use the National Fire Protection Association (NFPA) and Hazardous Materials Identification System (HMIS) systems, or even devise their own custom labels.14 Additionally, the ANSI labeling standard is often used in

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12 https://www.osha.gov/dsg/hazcom/ghs.html
13 49 CFR 172, Subpart E.
14 https://www.osha.gov/dsg/hazcom/ghs.html
developing consumer labels. With all of these competing symbols, it seems unlikely the average consumer could understand or find meaning in any particular symbol.

To further illustrate the complexity of the system, OEHHA should consider the fact that the GHS manual is a 561-page volume. According to OSHA, formal training is needed to implement this system.

Another area of confusion exists as to what individual symbols mean. There are “different labels for different sectors and different target audiences.” For example, under the GHS system, a red diamond with an exclamation mark can refer to any of the following: “Irritant, Dermal Sensitizer, Acute toxicity (harmful), Narcotic Effects, Respiratory Tract, [or] Irritation.” However, transport pictograms represent acute toxicity with a skull and cross bones.

In conclusion, there are many problems with the GHS system that will lead to consumer confusion. The complexity of the system, the lack of clarity in the pictograms and the competing systems will all work against the goal of better informing Californians of potential chemical hazards.

**Recommendation:** We recommend that OEHHA not include the GHS pictogram on the warning requirements and instead continue to use “WARNING” to inform the consumer.

**Reporting Requirements**

Draft proposed Section 25604(a) would require, “[t]he type of environmental exposures the warning is intended to cover, if any, and the affected area”; “[w]hether the warning is being provided for cancer, or birth defects or other reproductive harm, or both”; “[t]he anticipated route, routes, or pathways of exposure to the listed chemical for which the warning is being provided”; “[r]easonably available information concerning the anticipated level of human exposure to the listed chemical, if known”; and “[i]nformation concerning actions a person can take to minimize or eliminate exposure to the listed chemical, if any.”

These proposed requirements create many uncertainties. The pre-proposal language also is unclear regarding how responsibility is apportioned for complex durable goods. Who is

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15 Ibid.
16 https://www.osha.gov/dsg/hazcom/HCSFactsheet.html
17 https://www.osha.gov/dsg/hazcom/ghs.html
18 Ibid.
19 Ibid.
responsible for the testing? Under what and how many different conditions? For a complex good like an automobile, would enclosed components be subject to testing? What entity would evaluate the adequacy of the tests? At what point in the supply chain would testing be required? Would this testing apply to new products, or products already in commerce?

For example, is the manufacturer of the complex durable good responsible for determining if there is potential exposure from any of the thousands of components as they are shipped from the supplier or is the supplier responsible for providing that information to the manufacturer? If it is the end manufacturer, then is that manufacturer responsible for determining if there is exposure to any Prop 65 chemicals only after all of the components have been assembled into the completed product? These questions need to be considered carefully before OEHHA proceeds with a proposal that is confusing and places responsibility for compliance with the wrong parties.

**Disclosure of 12 Chemicals**

Section 25605 of the draft proposal specifies 12 chemicals that must be identified if they are present: (1) acrylamide; (2) arsenic; (3) benzene; (4) cadmium; (5) chlorinated tris; (6) 1,4-dioxane; (7) formaldehyde; (8) lead; (9) mercury; (10) phthalates; (11) tobacco smoke; and (12) toluene. OEHHA has not provided clear criteria as to how and why the 12 specific chemicals were chosen. The only reason appears to be OEHHA’s sense that the public “recognize[s] these names.” Furthermore, OEHHA has not provided any criteria for meeting exposure threshold levels for these chemicals, nor a *de minimis* level. OEHHA has not clarified that this proposal does not apply to unintentionally-added chemicals or by-products; and has not established criteria for data quality.

It is also confusing that OEHHA selected these “Top 12” chemicals as priorities, yet they do not align with the Department of Toxic Substance Control’s SCP program’s first list of product-chemical combinations. If both of these California regulations purport to communicate and eliminate bad actors, why do we need both and what is the primary concern? If OEHHA plans to eliminate consumer confusion, the first step should be to streamline requirements between Prop 65 and the SCP regulations to identify priorities and provide consistent messaging, reduced duplication, and a single label.

Additionally, the current regulation requires one warning, yet the draft proposal does not specify what steps should be taken if more than one of the 12 chemicals are identified—how is disclosure handled? And, if the product contains one or more of the 12 chemicals plus any of the other Prop 65 chemicals, how should the product be labeled? The more

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20 From the OEHHA Pre Regulatory Workshop, April 14, 2014.
complex the product, the higher the likelihood it will contain multiple Prop 65-listed chemicals among its components. The draft proposal must clarify how to handle labeling for multiple chemicals and clearly describe how to label for complex products (i.e., a single label for the product in entirety).

CONCLUSION

Global Automakers and the Auto Alliance appreciate OEHHA’s effort to improve Prop 65 by making the warning requirements more meaningful to the public. OEHHA’s pre-regulatory proposal, however, has not yet provided a workable and realistic framework.

Complex durable goods do not lend themselves practically to the types of warning label requirements that OEHHA is considering and therefore these potential changes are unreasonably burdensome. In addition to concerns relating to complex durable goods, we also find the proposal to be so vague and unclear that it presents an unworkable framework that will be impractical to implement.

Throughout these comments, we have provided several recommendations:

• Maintaining the current wording because it more accurately characterizes (and will not mislead the consumer about) the potential exposure to the chemical;
• Foregoing inclusion of the GHS pictogram on the warning requirements and instead continue to use “WARNING” to inform the consumer;
• Considering a streamlined and harmonized approach to reduce the number of labels;
• Providing three years lead time to implement any new warning requirement provision;
• Providing additional time for any reporting requirements, with an option for additional flexibility in timing if needed;
• Providing an explicit exemption from the warning requirements for replacement parts used to repair vehicles as produced;
• Not requiring manufacturers to provide exposure information; and
• Not requiring specific labels for complex durable goods and clarifying that a single, general notification, such as a warning in the owner’s manual, continues to comply with the Prop 65 warning requirements.

We encourage OEHHA to consider the distinctive differences between the vast variety of products it is trying to regulate, as well as the complexity of the requirements that would be imposed. OEHHA should reevaluate and revise the pre-proposal and should allow for another round of public comment before proceeding with the regulatory process.
We thank you for considering the arguments presented herein. Please do not hesitate to contact us with questions or if I may provide additional information. We look forward to working with OEHHA as it moves forward.

Sincerely,

Stacy Tatman  
Manager, Environmental Affairs  
Alliance of Automobile Manufacturers  
202.326.5551  
statman@autoalliance.org

Julia M. Rege  
Senior Manager, Environment and Energy  
Association of Global Automakers, Inc.  
202.650.5559  
jrege@globalautomakers.org