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Re: Comment to Proposed Amendments to Article 6 Clear and Reasonable Warnings – Short Form; OEHHA Proposition 65 Regulations

To whom it may concern,

This letter is sent to provide comment on the above-mentioned proposed rulemaking, namely proposed amendments to the California Code of Regulations, Title 27, Article 6, which set forth the requirements surrounding the use of "short form" warnings by manufacturers of goods to ensure compliance with the requirements of the Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly known as "Proposition 65" or "Prop 65"). Because SIG SAUER finds that the Act and its implementing regulations do not provide sufficient guidance on manufacturers' duty to determine whether an exposure to a listed chemical is occurring, and because we believe that the proposed amendments would result in significant increased costs for manufacturers (unlike the Office's finding that the proposed amendments would result in no additional significant costs), SIG SAUER believes that the proposed amendments pose significant issues that need to be addressed before implementation.

<u>The Proposed Amendments introduce unacceptable uncertainty for manufacturer compliance</u>

The provision at the heart of the Act in relation to consumer goods is Sec 25249.6, which states that "no person . . . 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 . . ."

Notably, the Act does not define the terms "knowingly" or "intentionally", however the Office's regulations *do* provide a definition of "knowingly". This definition is contained at 27 CCR 25102(n), and defines knowingly as follows: "'knowingly' refers only to knowledge of the fact that a . . . 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. However, a person in the course of doing business who, through misfortune or accident and without evil design, intention or negligence,

commits an act or omits to do something which results in a discharge, release or exposure has not violated Section 25249.5 or 25249.6 of the Act."

The definition of "knowingly" makes it clear that an actor will be deemed to be in knowledge of an exposure that must be warned of merely if it knows that the exposure is occurring, regardless of whether or not the exposure is unlawful. However, what this definition notably lacks is any exposition of when the State will attribute knowledge to that actor. Is an exposure "knowing" only when a manufacturer has direct knowledge that an exposure is occurring, or does a manufacturer have a duty to investigate the materials, parts, components, products it receives from suppliers to determine whether such goods contain a listed chemical and pose an exposure risk?

Under the current regulations, many manufacturers have implemented a policy whereby all products for which they do not have knowledge of a specific risk of chemical exposure are labeled with the currently approved short form warning. A practice which is in fact a stated impetus for the proposed amendments. However, without further definition or clarification around what is a "knowing and intentional" exposure – specifically clarifying what duty a manufacturer has to determine whether sourced goods or components pose a risk of exposure – the proposed changes to Article 6 will leave manufacturers in a state of confusion as to exactly what they must do to remain in compliance with the Act.

<u>The Proposed Amendments will have a significant economic impact on businesses</u>

In its Initial Statement of Reasons for the proposed amendments to Article 6, the Office states "the proposed regulatory action will not have a significant adverse economic impact directly affecting businesses . . ." as, "the action does not impose any new requirements upon . . . businesses because the safe harbor regulations are non-mandatory guidance."

This statement by the Office implies that manufacturers should already have incurred all potential costs associated with determining (1) whether its products contain a specific listed chemical, and (2) labeling them as such. However, the Office's own statements as to the reason the proposed amendments are needed show that such is generally *not* the case.

Specifically, in the Initial Statement of Reasons, the Office states that one concern leading to the need for the Proposed Amendments is the practice of manufacturers using the short form warning on products which they do not know to pose any risks of an exposure to a listed chemical. The ubiquity of the short form warning across consumer goods in multiple industries would indicate that this is a widespread practice.

The widespread use of the short form warning indicates that manufacturers have relied on the ability to use the short form warning - currently allowed and acceptable under the Act and its implementing regulations - to remain in compliance, and would not yet have incurred significant costs in either (1) determining whether or not their products could result in an exposure to a listed chemical beyond knowledge already in hand, or (2) managing the implementation of the inordinately more variable number of labels and product packagings that will be necessary to include appropriate, specific listed chemical

warnings. Although as the Office states, the short form warnings are "non-mandatory" in nature (i.e., they are an alternative to a full warning), their use is currently not restricted in any manner, and therefore the inclusion of such an option by its very nature means that manufacturers have specifically *not* been required to incur costs associated with these actions. Further, even if manufacturers were required to, or had, incurred the costs related to (1) above, dispensing with the current short form warning option would cause manufacturers using the short form warning to incur the costs related to implementing more varied and specific warning statements on their products regardless – costs which are not insignificant. As such, the Proposed Amendment actually *does* represent a significant adverse economic impact on businesses, and requires them to incur new, significant costs which are not obligated under the current regulations.

Due to the confusion that is present under the Act in relation to the duty manufacturers have to determine whether or not a product poses a risk of exposure to a listed chemical (as discussed above), and due to the varied nature of manufacturers' businesses (and how diverse their product offerings might be), the extent of new cost to a manufacturer cannot be precisely defined and will be widely variable. However, it is likely that for most manufacturers the added cost will be significant.

Take for example, SIG SAUER. If the proposed amendments are implemented, SIG SAUER estimates that over 10,000 unique product SKUs will need to be evaluated regarding how to update the Prop 65 warning statement in accordance with the proposed amendments – warnings that are directly printed onto the product packaging or included as a sticker. Once these evaluations and associations are completed, tooling and sources for these product packagings and labels will need to be developed, and processes to ensure that the products are packaged with the appropriate warnings implemented.

These activities would incur significant costs in the following ways for SIG SAUER:

- Depending on what exact duty a manufacturer has to account for the presence of listed chemicals in its products - increased supplier management costs associated with ensuring that information is obtained from all suppliers about the presence of listed chemicals in their goods or potentially hiring a staff chemist;
- Increased time and manpower devoted to developing and managing newly required, unique warning statements on current and future goods;
- Costs required to revise all current product packagings and labels that utilize the currently approved short form warning;
- Increased costs associated with an inability to use common packaging, and the development of additional specific packaging materials;
- Increased costs associated with sourcing packaging in lesser quantities due to increased packaging variance; and
- Increased costs associated with the added complexity of ensuring products are packaged with the proper warning, and inevitable increased fallout and rework due to errors and mistakes in the packaging process.

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Although these costs cannot be specifically defined or determined at this time, it can be said with certainty that they will be significant, and will not be merely a one-time cost, but a continued carrying cost for SIG SAUER, as they would be with other manufacturers.

For these reasons, SIG SAUER respectfully requests that the office reconsider the proposed amendments and table their implementation, until further clarity to the requirements of the Act is provided, and a detailed review of the real costs that the proposed amendments represent to the many manufacturers who have relied on the regulations as currently written for years is completed.

Sincerely,

Tim Lachance
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