

## Product Regulation & Liability - USA

### For better or worse: OEHHA solicits input on Proposition 65 revisions

Contributed by [Morrison & Foerster LLP](#)

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#### Introduction

Earlier in 2014 California's Office of Environmental Health Hazard Assessment (OEHHA), which is charged with implementation of the state's controversial Proposition 65 law, released a pre-regulatory proposal to revise its longstanding regulations governing "clear and reasonable warnings". The proposal met with substantial opposition from a broad coalition of businesses and, as a result, OEHHA is expected to unveil a new slimmed-down version later this autumn. In the interim, to address other criticisms of its previous proposal, OEHHA recently requested that the public submit comments, by November 17 2014, on several other aspects of the regulations.

#### Areas of input

OEHHA's request focuses on key aspects of the few defences available in Proposition 65 cases:

- Ability to average test results and product use when calculating levels of exposure<sup>(1)</sup> – does any single exposure to a product containing a listed chemical trigger the warning requirement or does the law look to the average exposure that is relevant to the health effect of that chemical? Must the decision to warn be based on the highest concentration of a chemical ever found in a product or does the law look to the average amount of the chemical in the product? To date, courts have determined the proper approach based on the evidence presented at trial. OEHHA's request seeks comment on whether it should issue regulations on these issues.
- Exemption for naturally occurring chemicals in foods<sup>(2)</sup> – the regulations have long recognised that a business should not have to warn about exposure to a listed chemical in food if the chemical is "naturally occurring" and reduced to the "lowest level currently feasible". However, the showings necessary to prove this exemption have been heavily contested in litigation. In addition, the California Attorney General's Office has objected to a number of settlements in which the parties had otherwise agreed to a specified naturally occurring allowance. If the views of the California Attorney General's Office and most plaintiffs are adopted, relying on this defence would be a risky proposition, rendering it of little benefit, if any.
- Alternative risk levels for chemicals in foods due to cooking<sup>(3)</sup> – the current regulations are silent on the criteria for calculating these levels, making their use for the purposes of determining compliance an uncertain exercise – whether in determining whether a business must warn or in defending an enforcement action. Even if such alternative levels can theoretically be employed in place of the statute's default assumption of a one in 100,000 cancer risk level, they have no impact on the level of exposure at which warnings for chemicals listed for reproductive harm are required.
- Safe use determinations<sup>(4)</sup> – these are essentially declarations by OEHHA that a product does not need a Proposition 65 warning based on its review of a technical submission. They are extremely rare, due to uncertainty regarding the standard of proof required, the time and cost involved, and general concern regarding the risks, reliability and utility of the process.

In addition to requesting comment on the need for revisions to these aspects of the existing Proposition 65 regulations, OEHHA has requested public input on:

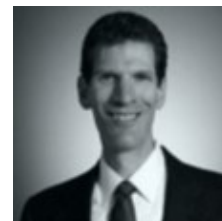
- where additional "interpretive guidance" is needed relative to Proposition 65;
- chemicals to be prioritised for the development or update of Proposition 65 'safe harbour' levels; and
- how data on post-natal exposure should be used for the purposes of Proposition 65.

#### Comment

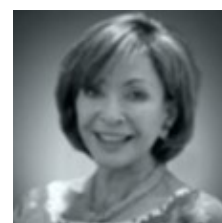
OEHHA will hear feedback on these issues from the public enforcement community, environmental

#### Authors

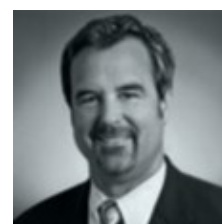
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groups and lawyers whose practices are devoted to bringing private Proposition 65 enforcement actions. It is therefore essential that OEHHA receive thoughtful, specific, well-supported feedback from the regulated community concerning the strengths and weaknesses of the current regulations and obtain businesses' suggestions on how they can be improved. If OEHHA revises the regulations, litigation over the outcome is likely; so to preserve their option to challenge any changes that make it harder for them to defend themselves, businesses will need to demonstrate that they made their case in the administrative record. Because statutory amendments of Proposition 65 are difficult, if not impossible, to obtain, this process may well determine the shape and impact of this much-feared law for many years to come.

For further information on this topic please contact [Robert Falk](#), [Michèle Corash](#) or [Michael Steel](#) at Morrison & Foerster LLP by telephone (+1 415 268 7000), fax (+1 415 268 7522) or email ([rfalk@mfo.com](mailto:rfalk@mfo.com), [mcorash@mfo.com](mailto:mcorash@mfo.com) or [msteel@mfo.com](mailto:msteel@mfo.com)). The Morrison & Foerster website can be accessed at [www.mofo.com](http://www.mofo.com).

#### Endnotes

- (1) 27 CCR Sections 25701, 25721, 25801, and 25821.
- (2) 27 CCR Section 25501.
- (3) 27 CCR Section 25703(b).
- (4) 27 CCR Section 25204..

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