Product labeling challenges arise when frameworks conflict: human factors considerations illustrated through recent glyphosate developments

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The conflict between EPA and California's OEHHA regarding allowable Proposition 65 warning language on glyphosate labeling may be approaching a resolution. However, over the course of the last several years, litigation regarding cancer warnings on glyphosate-containing products has been ongoing, and a federal appeals court in May 2021 upheld a judgment against a manufacturer of a glyphosate-containing pesticide for not providing cancer warnings on its product labeling.¹⁸ Warnings decisions in the face of conflicting frameworks and carcinogenicity determinations continue to be a challenging issue. Some human factors considerations that may be helpful to deliberations about when and how to warn are highlighted below.

Human factors and risk communication frameworks Regulatory frameworks that designate thresholds for communicating information can limit informational load while also reducing the potential for informational "noise" and false alarms.¹⁹ Designated thresholds for communicating information are one means by which the overuse of warnings (e.g., provision of messages related to low-level, low probability, or speculative risks) can be reduced. Potential problems associated with the overuse of warnings identified in the literature include:²⁰

• Reduced attention to warnings, generally • Reduced attention to individual messages within warnings • Reduced recall of certain warning messages • Reduced believability/credibility of warnings • Reduced ability to differentiate the relative magnitude of risks • Misplaced reliance on completeness of warnings

In the absence of established thresholds for warning, or in the presence of conflicting guidance, human factors considerations related to information load and the potential for informational noise and false alarms are still relevant, and limiting information about unestablished or lowlevel-risks can still be beneficial. Considerations may include whether there is consensus or disagreement regarding a stated health effect, whether the presence of a potentially hazardous **ingredient** constitutes an actual **risk**, and the regulatory authority of agencies involved.

Proposition 65 warning thresholds: OEHHA notes that they are bound by law to put IARC 2A carcinogens on the Proposition 65 list of substances known to the State of California to cause cancer, but **OEHHA regulations do establish a threshold** for when products containing these chemicals must bear a warning.^{21, 4} The challenge, however, is that determinations of whether exposure thresholds may be exceeded for a given product may involve professional judgment and OEHHA places the burden of proof on manufacturers. OEHHA has expressed concern about "over-warning" and the "unnecessary proliferation of Proposition 65 warnings," citing the value of "truthful, accurate information,"²² but industry members subject to these regulations have faulted OEHHA for creating "a system in which any unlabeled product is subject to litigation and financial penalty...forc(ing) companies to use labeling as their only recourse to protect their business."²³ In the case of Proposition 65, the presence of a threshold does not necessarily counter the potential for confusion and warnings overuse that can arise from these regulations.

- 27 CCR Article 6, Clear and Reasonable Warnings. September 2008.
- 27 CA ADC 25603. Consumer Product Exposure Warnings Content. Retrieved from https://govt.westlaw.com/calregs
- United States Environmental Protection Agency (EPA) (2017). Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential. December 12. 10. Tarantino, W. (2018). Round One Goes to Roundup: Court Temporarily Enjoins Proposition 65 Warnings for Glyphosate and Glyphosate Residues in Foods. March 5. Accessed 9/16/22
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- 12. EPA (2019). EPA Takes Action to Provide Accurate Risk Information to Consumers, Stop False Labeling on Products. News Release. August 8.
- 13. EPA (2020, January). Glyphosate: Interim Registration Review Decision, Case Number 0178. Docket EPA-HQ-OPP-2009-0361. 14. Renda, M. (2020). Judge Halts California Bid for Cancer Warning on Roundup. Retrieved from https://www.courthousenews.com/judge-halts-california-bid-for-cancer-warning-on-roundup/
- 15. Freedhoff (2022). Letter from Dr. Michal Freedhoff (EPA Assistant Administrator) to Dr. Lauren Zeise (OEHHA Director) dated April, 8, 2022. 16. OEHHA (2022a). Notice of Modification to Proposed Regulation and Addition of Documents to Rulemaking File. Title 27, California Code of Regulations New Sections 25607.48 and 25607.49
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- Meeting, pp. 916-920. 21. OEHHA (2017, June 16). Letter to Monsanto Company re: Petition for Reconsideration of the Proposition 65 Listing of Glyphosate Pursuant to the Labor Code Mechanism.
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nmental Health Hazard Assessment (OEHHA) (2017). Notice to Interested Parties July 7, 2017. Chemical Known to the State of California to Cause Cancer: Glyphosate. July 7

California Health and Safety Code, Division 20, CHAPTER 6.6. Safe Drinking Water and Toxic Enforcement Act of 1986 [25249.5 - 25249.14]. Retrieved from https://leginfo.legislature.ca.gov/ OEHHA (2018). Final Statement of Reasons. Title 27, Section 25705 (b) Specific Regulatory Levels Posing No Significant Risk. No Significant Risk Level: Glyphosate. April 10.

Glyphosate was originally registered by the EPA in 1976, and since then the carcinogenic potential of glyphosate has been evaluated by EPA several times starting in the 80s.

^{18.} United States Court of Appeals for the Ninth Circuit. (2021, May 14). Opinion in Hardeman v. Monsanto, Case Nos. 19-16636, 19-16708, 3:16-cv-00525-VC, and 3:16-md-02741-VC.

^{19.} Shah, R.J., Hall, S.M., & Diebol, J.K. (2016) Contextual considerations for the development and assessment of warnings. Proceedings of the XXVIIIth Annual Occupational Ergonomics and Safety

^{20.} Frantz, J.P., Rhoades, T.P., Young, S.L., & Schiller, J.A. (1999). Potential Problems Associated with Overusing Warnings. Proceedings of the Human Factors and Ergonomics Society 43rd Annua

^{22.} OEHHA (2021, January). Initial Statement of Reasons, Title 27, California Code of Regulations, Proposed Amendments to Article 6 Clear and Reasonable Warnings: Short-Form Warnings for

^{23.} American Apparel & Footwear Association (AAFA) (2022, April 20). Letter to OEHHA re: Second Notice of Proposed Modified Amendments to Article 6, Clear and Reasonable Warnings Short