

January 19, 2022

Lauren Zeise, Ph.D.
Director Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
1001 I Street
Sacramento, California 95814

Re: Notice of Modification to Text of Proposed Regulation Title 27, California Code of Regulations
Proposed Amendments to Article 6 Clear and Reasonable Warnings – Short Form

Dear Dr. Zeise,

Thermo Fisher Scientific thanks the California Office of Environmental Health Hazard Assessment for the opportunity to comment on the proposed rulemaking. We support the intent to make Proposition 65 more effective in protecting human health from environmental exposures to chemicals known to the State of California as carcinogenic or toxic for reproduction.

Thermo Fisher Scientific is the world leader in serving science. Our mission is to enable our customers to make the world healthier, cleaner and safer. Whether our customers are accelerating life sciences research, solving complex analytical challenges, improving patient diagnostics and therapies or increasing productivity in their laboratories, we are here to support them. As both a large downstream manufacturer of finished goods (articles and equipment) and a producer and distributor of chemical products and laboratory reagents in addition to diagnostic devices within the State of California, we support the intent of the proposed amendments to improve clarity of communication to consumers regarding the presence of Proposition 65 List chemicals in products.

Chemical products and laboratory reagents within the biotechnology, diagnostic, research and education sectors are typically supplied in small containers with capacities of 100 ml or less and, frequently, in very small containers with capacities of < 2 ml containing only a few microliters of reagent. In addition to Proposition 65, these products must also comply with specific federal labeling requirements specified under the U.S. Hazardous Communication Standard (HCS) (29 CFR 1910.1200) and any applicable sectorial legislation (e.g., The U.S. Food, Drug, and Cosmetic Act). The federally mandated content already challenges manufacturers of these small products. The inclusion of a longer Proposition 65 warning will only further clutter the label, potentially reducing clarity rather than enhancing it. This is particularly true in those instances where the requirement provides only redundant information to federal statutes, creates potential for confusion or difficulties for consumers trying to identify the necessary warning, and creates substantial practical difficulties in modifying the existing labels.

In accordance with the Federal HCS, these labels bear warnings regarding the hazardous properties of the products as well as the identity of any carcinogenic or toxic for reproduction substances present (in addition to, where applicable, the existing Proposition 65 Short-Form Warning). Thermo Fisher Scientific recognizes the unique requirement to provide adequate warnings for those substances

recognized by the State of California as having different toxicological endpoint(s) or where exposure is lower than that recognized for labelling under the Federal HCS. However, the inclusion of additional Proposition 65 warning text that merely restates these toxicological endpoints and repeats the substance(s) names that are included on the label appear to be superfluous and would impart no useful additional information to the California consumer.

Incorporating the proposed extended Proposition 65 short-form warning texts on small containers, where the labels already contain the federally mandated information, could also make it more difficult for the consumer to identify pertinent safety information regarding their use of the products. If the Proposition 65 warnings merely replicate the federally mandated information already on the label, there is real potential for confusion and loss of clarity (especially if the label is already at the minimal font size and is extremely cluttered). While still redundant (in most cases), the current Short-Form Warnings take up less space on the label and provide an on-line reference to where users may obtain additional information.

Incorporating the proposed extended Proposition 65 short-form warning texts on very small containers, which already contain relevant and aligned information such as the toxicological endpoints and substance identity, does not provide unique or additional warning to the consumer. Modifying these labels to contain this redundant information may reduce clarity and make it impossible to package the product (e.g., by use of fold-out labels, transferring to larger containers or using secondary labels that can be disconnected from the product). This will potentially threaten the availability of critical diagnostic and research tools in the California market. We ask OEHHA to consider practical derogations for very small products which are classified and labelled according to the U.S. Federal HCS and/or sectorial legislation and are aligned with the State of California classification under Proposition 65.

Thank you for the opportunity to provide these comments. Please contact me if I can provide further information.

Best Regards,

A handwritten signature in black ink, appearing to read "Jeff Schatz". The signature is fluid and cursive, with the first name "Jeff" being more prominent than the last name "Schatz".

Jeff Schatz
Director, Global Product Legislation Compliance
Thermo Fisher Scientific