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September 8, 2026

Comment Submission: Draft Regulatory Language Omnibus 2026

Dear Dr. Thayer,

NSF appreciates the opportunity to provide comments on the proposed regulatory changes included in Proposition 65 Omnibus Rulemaking (2026). Founded at the University of Michigan School of Public Health in 1944, NSF is an independent global public health and safety organization dedicated to protecting and advancing human health. NSF develops consensus-based standards and provides testing, inspection, certification, auditing, education, consulting, and related services across a broad range of industries.

NSF's scientific and technical staff includes toxicologists, chemists, microbiologists, engineers, auditors, and public health experts who support regulatory compliance, product stewardship, and human health risk assessment activities in more than 110 countries. Through its ISO/IEC 17025-accredited laboratories, NSF conducts analytical testing, certification, technical evaluations, and risk assessments relevant to the assessment of chemical exposures and the protection of public health.

We appreciate OEHHA's continued efforts to ensure that Proposition 65 remains protective of public health while reflecting current scientific understanding. We support the objective of providing greater clarity regarding the scope of the naturally occurring exemption. However, we are concerned that the proposed amendment to Section 25501(a)(3) may unintentionally create regulatory uncertainty and could capture a broad range of traditionally prepared botanical ingredients that have not undergone chemical modification and whose safety profile would more appropriately be evaluated based on an exposure-based risk assessment.

The proposed language states:

> "A listed chemical which has been extracted or concentrated from any source, such as a plant, may be present in a product as the result of human activity even if the extraction or concentration did not change the Chemical Abstract Services Registry Number."

As drafted, this provision is extremely broad and does not clearly distinguish between highly selective extraction processes designed to isolate specific constituents and conventional processing methods that have been used for decades, or in some cases centuries, to prepare foods, dietary supplements, cosmetic

ingredients, and botanical products. Because nearly every botanical ingredient undergoes some degree of processing before use, the proposal could be interpreted to encompass ordinary activities such as drying, steeping, pressing, filtering, concentrating, steam distillation, or solvent extraction.

From a public health perspective, the critical question should not be whether human activity occurred at some point during processing, but whether the processing fundamentally changed the nature of the chemical exposure or created a materially different hazard profile than that associated with the original source material. A process that merely transfers or concentrates the naturally occurring constituents present in a botanical should not necessarily be treated the same as a process that intentionally isolates, enriches, synthesizes, or chemically modifies a constituent to create a substantially different exposure scenario.

This distinction is increasingly reflected in international regulatory approaches to naturally derived materials. In the European Union, recent cosmetic regulatory initiatives have focused on improved characterization, assessment, and management of naturally derived substances while recognizing the continued use of complex natural mixtures and conventionally processed botanical preparations. Regulation (EU) 2024/2865 and the European Commission's proposed amendments to Article 15 of the Cosmetics Regulation emphasize scientific evaluation and risk assessment rather than categorically distinguishing substances solely on the basis of whether they have undergone processing. Likewise, recent SCCS evaluations of naturally derived fragrance constituents and related materials, including acetophenone, heliotropin, cuminaldehyde, and p-cymene, have focused on toxicological characteristics and exposure-based risk assessment rather than the mere fact that a constituent may be obtained through extraction from a natural source.

A similar risk-based approach would better support public health objectives under Proposition 65. Basic processing methods frequently serve important functions, including improving microbial safety, product consistency, consumer usability, and quality control. Processes such as steam distillation, cold pressing, aqueous extraction, hydroalcoholic extraction, drying, or concentration often preserve the naturally occurring composition of the source material rather than creating a new chemical entity. Treating all such processes as potential evidence that a listed chemical is present "as the result of human activity" could inadvertently blur the distinction between naturally occurring constituents and chemicals that are added, generated, or intentionally isolated through manufacturing.

We are also concerned that the lack of specificity could create uncertainty across multiple sectors, including foods, dietary supplements, cosmetics, personal care products, fragrances, and other consumer products that utilize botanical ingredients. Common processing activities such as water removal, pressing, milling, grinding, extraction, and concentration can increase the relative concentration of naturally occurring constituents without altering the chemical identity of those constituents. Without clearer boundaries, businesses may face difficulty determining which conventional preparation methods preserve naturally occurring status and which trigger additional compliance obligations. This has potential to result in Proposition 65 warning labelling becoming ubiquitous for cosmetic and food products across the board

to address the ambiguity, which dilutes the overall purpose of the warnings. Such uncertainty ultimately detracts from the public health goal of focusing attention and resources on exposures that may present meaningful risk.

Accordingly, we encourage OEHHA to revise the proposed language to expressly distinguish traditional or conventional botanical preparation methods from processes that intentionally isolate or substantially enrich specific constituents. Providing this clarification would be consistent with the longstanding focus of Section 25501 on the origin of a chemical and whether human activity created, added, or materially altered that chemical, rather than whether some level of routine processing occurred after harvest. Such clarification would better align the regulation with current scientific practice, support public health objectives, and reduce unnecessary uncertainty for stakeholders while maintaining appropriate protections for California consumers.

For these reasons, we respectfully request that OEHHA revise the proposed amendment to provide clear and objective criteria distinguishing conventional botanical preparation methods from processes that intentionally isolate, concentrate, or create specific chemical constituents.

Sincerely,

Harold Chase

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Director of Government Affairs