CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

September 8, 2026

Dr. Kristina Thayer, Director
Office of Environmental Health Hazard Assessment
1001 I Street, 23rd Floor
P.O. Box 4010
Sacramento, California 95812-4010
Via electronic submission to: https://oehha.ca.gov/comments

RE: COMMENTS ON PROPOSED AMENDMENTS TO TITLE 27, CALIFORNIA CODE OF REGULATIONS

Dear Dr. Thayer:

The Consumer Healthcare Products Association (CHPA)[1] appreciates the opportunity to provide comments on the Office of Environmental Health Hazard Assessment's "omnibus" proposals for amendments to Title 27 of the California Code of Regulations implementing Proposition 65.

1. **OEHHA Should Withdraw the Proposed Amendment to Section 25501 and Rescind Its December 16, 2025, Letter**

CHPA appreciates OEHHA's interest in providing greater clarity regarding the scope of the naturally occurring exemption as this is important to several of our member companies. Consumer healthcare products (over-the-counter ("OTC") medicines, dietary supplements and consumer medical devices)) and their ingredients may contain listed chemicals that originate in the plant, animal, soil, or other natural environment from which the food or botanical material is derived. Those foods and botanical materials also routinely undergo ordinary processing before reaching consumers in consumer healthcare products, including drying, milling, pressing, extraction, concentration, roasting, and other forms of manufacture. Section 25501 has long provided the framework for determining what portion of a listed chemical in those products constitutes an "exposure" under Proposition 65, including, under subdivision (b) listed chemicals carried into non-food products (e.g., consumer healthcare products).

The proposed amendment would materially change that framework and the settled understanding of the naturally occurring regulation. The proposal would add language stating that 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." In doing so, the proposal shifts the naturally occurring

[1] CHPA, founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter ("OTC") medicines, dietary supplements, and OTC medical devices. For more than 145 years, CHPA has served as a vital advocate for the consumer healthcare products industry. CHPA members provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases. www.chpa.org

inquiry away from the source of the listed chemical and toward the processing of the food containing it.

That shift has substantial consequences for consumer healthcare products, and their ingredients, and is difficult to reconcile with the remainder of Section 25501. For the reasons discussed below, CHPA respectfully requests that OEHHA withdraw the proposed amendment and rescind its December 16, 2025, letter[2] concerning the naturally occurring regulation, which has introduced similar uncertainty into application of the existing regulation.

Section 25501(a)(3) currently provides that a chemical is naturally occurring "only to the extent that the chemical did not result from any known human activity," with specified exclusions for agronomic practices (sowing, planting, irrigation, plowing, and other mechanical preparation of soil) and one express inclusion (the addition of chemicals to irrigation water applied to soil or crops). OEHHA proposes to add the below highlighted sentence to subsection (a)(3).

> Section 25501. Exposure to a Naturally Occurring Chemical in a Food.
>
> (a) Human consumption of a food shall not constitute an "exposure" for purposes of Section 25249.6 of the Act to a listed chemical in the food to the extent that the person responsible for the exposure can show that the chemical is naturally occurring in the food.
>
> (1) For the purposes of this section, a chemical is "naturally occurring" if it is a natural constituent of a food, or if it is present in a food solely as a result of absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, or grown, or obtained; for example, minerals present in the soil solely as a result of natural geologic processes, or toxins produced by the natural growth of fungi.
>
> (2) The "naturally occurring" level of a chemical in a food may be established by determining the natural background level of the chemical in the area in which the food is raised, or grown, or obtained, based on reliable local or regional data.
>
> (3) A chemical is naturally occurring only to the extent that the chemical did not result from any known human activity. Where a food contains a chemical, in part naturally occurring and in part added as a result of known human activity, "exposure" can only occur as to that portion of the chemical which resulted from such human activity. For purposes of this section, "human activity" does not include sowing, planting, irrigation, or plowing or other mechanical preparation of soil for agricultural purposes; but does include the addition of chemicals to irrigation water applied to soil or crops. 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.

[2] California Office of Environmental Health Hazard Assessment to Mark Todzo, Lexington Law Group. December 16, 2025.

(4) Where a chemical contaminant can occur naturally in a food, the chemical is naturally occurring only to the extent that it was not avoidable by good agricultural or good manufacturing practices. The producer, manufacturer, distributor, or holder of the food shall at all times utilize quality control measures that reduce natural chemical contaminants to the "lowest level currently feasible," as this term is used in Title 21, Code of Federal Regulations, Section 110.110, subdivision (c) (2001).

(b) A person otherwise responsible for an exposure to a listed chemical in a consumer product, other than food, does not "expose" an individual within the meaning of Section 25249.6 of the Act to the extent that the person can show that the chemical was a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product. Where a consumer product contains a listed chemical, and the source of the chemical is in part from a naturally occurring chemical in food and in part from other sources, "exposure" can only occur as to that portion of the chemical from other sources.

a) Section 25501 Establishes an Integrated Framework for Determining Whether a Chemical Is Naturally Occurring

Proposition 65 requires a warning only where a business causes an "exposure" to a listed chemical. Section 25501 provides that human consumption of a food "shall not constitute an 'exposure'" to the extent the person responsible can establish that the chemical is naturally occurring in the food. The regulation therefore defines the extent of the exposure itself rather than simply excusing an exposure that has otherwise occurred.

The subdivisions of Section 25501 work together to answer that question.

First, subdivision (a)(1) identifies the circumstances in which a chemical may be naturally occurring. A chemical may be a natural constituent of the food itself, or it may be present because the food absorbed or accumulated the chemical from the environment in which it was raised, grown, or obtained, a contaminant. The regulation expressly identifies minerals naturally present in soil and toxins produced through the natural growth of fungi as examples.

Second, subdivision (a)(2) addresses how the naturally occurring level may be established, including through reliable local or regional background data.

Third, subdivision (a)(3) addresses the contribution of human activity. A chemical is naturally occurring "only to the extent that the chemical did not result from any known human activity." Where a chemical is present partly naturally and partly as a result of human activity, only the human-caused portion constitutes an exposure. The provision is thus expressly apportioning.

The examples included in subdivision (a)(3) are instructive. Sowing, planting, irrigation, plowing, and other mechanical preparation of soil for agricultural purposes are excluded from "human activity." By contrast, adding chemicals to irrigation water is expressly included. The evident distinction is whether human activity contributed the chemical to the food or its growing environment, not merely whether people engaged in some activity in producing the food.

Indeed, this was the distinction that the Court of Appeal relied on in rejecting a challenge to the naturally occurring regulation. *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 659 (1991) (finding that the relevant "sources indicate that Proposition 65 sought to regulate toxic substances which are deliberately added or put into the environment by human activity."). The Court read the "knowingly and intentionally" requirement of the statute to suggest that "some degree of human activity which results in toxins being *added* to the environment is required." *Id*. (emphasis added). And it noted, "A chemical is not 'put' into the environment if it is naturally occurring in, for example, fruits and vegetables." *Id.* The Court went on:

> Use of terms such as "knowingly and intentionally" and "putting" implies that human conduct which results in toxins being *added* to the environment is the activity to be controlled. The opponents of the initiative expressly indicated that only "man-made" substances would be regulated.

Id. at 660.

Fourth, subdivision (a)(4) provides an additional safeguard for naturally occurring contaminants (as opposed to constituents). A contaminant is naturally occurring only to the extent it could not be avoided through good agricultural or good manufacturing practices, and businesses must use quality-control measures that reduce naturally occurring contaminants to the "lowest level currently feasible."

Finally, subdivision (b) expressly carries the same principle into non-food consumer products, and it is the operative provision for consumer healthcare products. A person is not "expos[ing]" an individual to a listed chemical "in a consumer product, other than food," to the extent the person shows the chemical "was a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product." Where the chemical comes partly from a naturally occurring chemical in food and partly from other sources, only the other-source portion is an "exposure."

These provisions are not independent of one another. Together, they establish an integrated framework: identify the source of the chemical; determine whether and to what extent human activity contributed to it being added to the environment; and, for contaminants (as opposed to constituents), determine whether good agricultural or manufacturing practices could reduce that naturally occurring amount further.

b) The Existing Framework Has Been Applied to Naturally Derived Constituents That Remain Present Following Processing

Traditionally, the regulation has been read by both OEHHA and the courts to focus on *how* the chemical came to be present in the raw plant—whether it was introduced by pollution, pesticide use, or some other human intervention, as opposed to occurring through the plant's own natural biochemistry. What a business does after harvest—steam-distilling, vacuum-distilling, blending, concentrating—has been understood as processing that changes the form and concentration of an already naturally occurring chemical, not steps that convert a naturally occurring chemical into a human-caused one.

OEHHA's historical treatment of naturally occurring plant constituents illustrates how this framework has been understood in practice.

The clearest example is methyleugenol. In January 2002, OEHHA's Chief Counsel considered whether methyleugenol naturally present in basil and other herbs and spices retained its naturally occurring status after being separated from the plant and subsequently incorporated into another food or consumer product. OEHHA concluded that methyleugenol produced naturally by the plant was naturally occurring and that separation did not, by itself, alter that conclusion where the methyleugenol remained chemically unchanged. Consistent with the *Nicolle-Wagner* decision that interpreted and upheld the regulation as consistent with Proposition 65, the letter treated the origin of the chemical as central. Human processing that separated an already naturally occurring constituent from its source did not automatically mean that the constituent itself had "resulted from" human activity.

Many of the other listed food ingredients, along with methyleugenol, are fragrance and essential-oil materials incorporated into consumer healthcare products. Similar naturally derived flavor and fragrance constituents may remain chemically identical - retaining the same CAS Registry Number - as the source material moves from a whole plant to an oil, extract, powder, concentrate, or other processed ingredient, and as that ingredient is formulated into a finished consumer healthcare product.

These examples should not be read to confine the issue to isolated flavor compounds. The same principle applies throughout the consumer healthcare products industry. Nearly every consumer healthcare product undergoes some form of processing. Processing changes the form of these foods. It may also change the concentration of naturally present constituents by weight. For example, drying a grape to make a raisin may concentrate lead that is present in the fruit, just as using an extraction process on basil may increase the concentration of naturally occurring methyleugenol. In each case the processing changes the form and concentration of an already naturally occurring constituent; it does not create, add, or chemically alter the listed chemical, and it does not change the naturally occurring character of that chemical. Further, despite potential changes in form and concentration during processing, human exposure to the food ingredients in a consumer healthcare product would remain comparable to exposure from consuming the unprocessed food.

c) The Proposal Creates Significant Uncertainty and Conflicts with Long-Established Precedent

OEHHA's proposal would upend this settled understanding – that chemicals in food ingredients are naturally occurring if they are not added into the environment by humans. Lead from pollution is not exempt; however, lead of geologic origin, that has been taken up into the plant's fibrous tissues through natural biological processes, is exempt. And it is exempt regardless of whether it is later concentrated in a finished product by drying or some other form of food processing.

Indeed, the regulation is silent as to post-harvest processing of foods and food ingredients because those processes do not "put" any chemicals into the food ingredients. The regulation calls out certain

human actions as excluded from “human activity,” but those are all pre-harvest (“sowing, planting, irrigation, plowing, and other mechanical preparation of soil for agricultural purposes”). Post-harvest activities, which do not add any chemicals into the food, were implicitly not considered to be disqualifying “human activity.”

OEHHA’s proposal reverses this understanding, and particularly in the context of OEHHA’s 2025 letter, for the first time considers common post-harvest food processing such as “extraction or concentration” to be disqualifying. Without a definition, the following ordinary food-processing steps are all potentially captured: water removal (drying, dehydration, freeze-drying, evaporation, juice concentration), fraction separation (pressing, expelling, defatting, protein isolation, solvent extraction), size reduction (milling, grinding, pulverizing), thermal processing (roasting, which drives off moisture), and component removal (hulling, shelling, sifting, air classification). Every one of these increases the concentration of some chemicals (whether constituents or contaminants) in the finished product.

The same uncertainty extends to the processing methods that define consumer healthcare product manufacturing: steam and vacuum distillation of essential oils, solvent and CO_2 extraction of botanicals, expression of citrus peel oils, production of absolutes and concretes, and concentration or fractionation of plant-derived ingredients for skincare and fragrance. Each of these "extracts or concentrates" is a listed chemical from a plant.

It is unclear which of these activities OEHHA intends to reach and why. Businesses cannot determine whether their products fall within or outside the regulation, and OEHHA has provided no guidance for making that determination.

Furthermore, the naturally occurring regulation recognizes that there will be post-harvest processing of a food ingredient, but that such processing does entail “human activity” that takes the chemical out of the naturally occurring exemption. Subsection (b) expressly preserves the naturally occurring exemption where a naturally occurring chemical in food is carried into a consumer product through “manufacture, production, or processing.” The regulation therefore already contains a considered judgment that post-harvest processing does not, by itself, destroy naturally occurring status. The proposed sentence and subsection (b) conflict with each other. That conflict is acute for non-food consumer healthcare products. Subsection (b) exists only because naturally occurring chemicals in food are carried into consumer healthcare products through "manufacture, production, or processing," which necessarily includes the extraction and concentration steps the proposed sentence would now treat as disqualifying "human activity." Read together, the amendment would withdraw through subdivision (a)(3) the very exemption that subsection (b) grants, an internal contradiction that leaves consumer health product manufacturers with no way to reconcile the two provisions.

This uncertainty is not academic. Consumer healthcare product manufacturers must make compliance decisions across numerous ingredients and processing methods. The regulation should allow those directly affected to understand whether for example, drying a fruit, milling a grain, pressing an oil,

distilling an essential oil, concentrating a juice, or producing a plant or botanical extract changes the treatment of a naturally occurring constituent. The proposed language does not do so.

d) OEHHA Should Rescind the December 16, 2025, Methyleugenol Letter

CHPA separately requests that OEHHA rescind its December 16, 2025, letter and reaffirm that regulated businesses may continue to rely on the interpretation of Section 25501 reflected in OEHHA's January 8, 2002, letter.

Methyleugenol is naturally produced by basil and other herbs and spices, and extraction does not change its chemical identity or CAS Registry Number. OEHHA therefore concluded that separating methyleugenol from its natural source and adding it to another food or consumer product did not cause it to lose naturally occurring status.

That interpretation aligns with the text and structure in Section 25501. Extracting an existing chemical is not the same as causing it to exist. When a plant naturally produces a listed constituent, later separation or concentration—without creating, adding, or chemically altering it—does not change the chemical's source. Human activity produced the extract or concentrate, not the listed chemical within it. The chemical was not "put" into or "added" to the environment by human activity.

For more than two decades, regulated businesses have reasonably relied on the framework set out in OEHHA's 2002 letter. That reliance was justified because the letter was issued by OEHHA's Chief Counsel, aligned with Section 25501 and the principal court decision interpreting it, and remained undisavowed by OEHHA for more than 20 years.

The December 2025 letter offers no reason for abandoning that interpretation. Section 25501(a)(3) has not changed; it still asks whether the chemical *resulted* from human activity, not whether processing occurred after the chemical already existed. Nor does the letter explain how extracting an unchanged chemical makes it "result from" human activity when it was already present in the source material.

Consumer healthcare product manufacturers should not lose the benefit of longstanding agency guidance through informal correspondence issued to an enforcement organization while OEHHA pursues rulemaking on the same issue. Unless and until Section 25501 is lawfully amended, regulated businesses should be able to rely on OEHHA's prior interpretation of the existing regulation.

Accordingly, CHPA requests that OEHHA rescind its December 16, 2025, letter and reaffirm that the January 8, 2002, letter remains valid guidance under Section 25501. OEHHA should confirm that extraction or concentration of a naturally occurring listed chemical—without creating, adding, or chemically altering it—does not, by itself, constitute "human activity" under Section 25501(a)(3), and that businesses may continue to rely on the 2002 letter.

2. CHPA Supports a QR-Code Warning Safe Harbor, With Targeted Revisions to Preserve Its Utility (Sections 25601, 25602)

CHPA supports OEHHA's proposal to expressly allow QR codes for Proposition 65 warnings. Properly implemented, a QR-code safe harbor would modernize the warning regulations, reflect how consumers access product information, reduce unnecessary packaging changes, give businesses flexibility as requirements evolve, and help consumers access clearer warnings than many product labels can accommodate.

The proposal's practical value depends on maintaining a clear distinction between the notice displayed with the QR code and the warning provided after the code is scanned. As drafted, the proposal could require so much warning-specific information on the physical package as to undermine the benefit of delivering the substantive warning electronically. CHPA supports the proposal but recommends targeted revisions to ensure the safe harbor is workable in practice.

a) A QR-Code Safe Harbor Would Provide Meaningful Benefits to Businesses and Consumers

In 2016, OEHHA amended Article 6 to replace the prior generic safe-harbor warning with a chemical-specific format. Section 25603 required consumer product warnings to include a yellow triangle symbol, the bold, capitalized signal word "WARNING," identification of at least one listed chemical, applicable endpoint language, and the Proposition 65 URL. OEHHA also authorized short-form warnings, which it has since refined and restricted.

Section 25601(c) requires consumer product warnings to be prominently displayed on a label, labeling, or sign and sufficiently conspicuous to be seen, read, and understood under customary purchase or use conditions. Section 25602(a)(2) allows electronic warnings that automatically provide the warning before or during purchase, without requiring the purchaser to seek it out.

QR codes have long served as a practical way to deliver warning information, but OEHHA has not expressly codified them as a regulatory safe harbor. In the 2016 Final Statement of Reasons, OEHHA clarified that a compliant electronic warning may require a simple affirmative step—such as clicking a link or scanning a code—provided the consumer first receives reasonable notice that a warning exists.

OEHHA now proposes to add QR codes on signs, shelf tags, shelf signs, labels, or labeling as a safe-harbor option, with the substantive Proposition 65 warning provided when the consumer scans the code. CHPA supports this approach.

The most immediate benefit is preserving label space. Packaging for foods (dietary supplements) and consumer healthcare products already must accommodate federal and state requirements—including Nutrition Facts, Drug Facts, ingredient statements, allergen disclosures, net quantity, manufacturer information, and other content—within limited space. That burden can be especially acute for small-format products including for some dietary supplement and OTC medicine packaging.

The more significant benefit is flexibility. A printed Proposition 65 warning becomes part of the package artwork; if the relevant chemical changes because of a new listing, testing, sourcing,

formulation, or exposure analysis, the business may need to revise artwork, approvals, printing materials, inventory, and production schedules.

A QR-code warning reduces those burdens by placing the substantive warning on a webpage rather than in package artwork. The package can remain unchanged while the linked warning is updated to reflect the product's current Proposition 65 profile, turning warning changes into a content-management task rather than a packaging and inventory project.

The proposal would also benefit consumers by allowing warnings to be updated in real time for products already in distribution or in consumers' possession, without lead time, lag time, or recalls.

These are meaningful improvements, and CHPA supports creating an express QR-code safe harbor. However, targeted revisions are needed to ensure the method realizes those benefits.

b) The Signal Language Should Be Streamlined

OEHHA's proposal would require the QR code to be accompanied by a statement that reads:

> Proposition 65 Warning for [name of one or more chemicals]. For more information, scan the QR code.

A QR code without any explanation would not adequately alert consumers that it leads to Proposition 65 warning information. A simple signal such as "Prop 65 Warning" or "Proposition 65 Warning" would solve that problem. Requiring the signal to identify the chemical, however, goes further than necessary.

Naming the chemical on the package would keep that information embedded in the artwork, forcing manufacturers to revise labels when testing, sourcing, formulation, or exposure analyses change. That would significantly reduce the flexibility gained by placing the substantive warning online.

More fundamentally, the signal begins to resemble the warning the QR code is intended to replace. If the package must identify a Proposition 65 warning and the chemical, the QR code becomes little more than a link accompanying a conventional warning.

The method would therefore solve only part of the problem: the package would still contain chemical-specific content requiring revision when the chemical changes. The signal should identify the QR code's purpose, while the linked webpage provides the substantive warning.

CHPA therefore recommends that OEHHA require only a signal saying:

Proposition 65 Warning

or:

Prop 65 Warning

immediately adjacent to the QR code. Optional words such as “Scan for,” “California,” or “CA” could precede those terms. This would tell consumers that the QR code links to Proposition 65 warning information, while the full warning—including chemical identification required by Section 25603—would remain on the linked webpage.

CHPA agrees that the Proposition 65 warning should be immediately and prominently available after scanning, without requiring consumers to navigate multiple pages, menus, or other content. This is consistent with OEHHA’s electronic-warning principle that the warning must be readily available, not something the purchaser must search for.

c) OEHHA Should Establish a Durability Safe Harbor

Electronic warnings pose operational issues that printed warnings do not. A printed warning generally remains available for the product’s life, while a QR-code warning depends on functioning web infrastructure. Even responsibly maintained websites can briefly fail for reasons outside a business’s control.

The proposed regulation does not address temporary outages. Without clarification, such an interruption could be treated as a failure to warn despite reasonable maintenance, discouraging use of the QR-code safe harbor.

OEHHA should adopt a reasonable-maintenance standard. A business that reasonably maintains the linked webpage and preserves warning records should not lose safe-harbor protection because of a temporary technical interruption beyond its control. This approach is consistent with provisions recognizing that warnings need not reach each exposed individual. Health & Safety Code section 25249.11(f); 27 Cal. Code Regs. section 25600(d).

CHPA appreciates the opportunity to submit these comments and welcomes further discussion of these proposals with OEHHA.

Sincerely,

Jay Sirois, Ph.D.
Vice President, Scientific and Regulatory Affairs