



September 8, 2026

Dr. Kristina Thayer, Director
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Via electronic submission to: <https://oehha.ca.gov/comments>

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

Dear Dr. Thayer:

Fragrance Creators Association (“FCA”) 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. FCA recognizes the considerable time and effort OEHHHA has devoted to developing the discussion draft and appreciates OEHHHA’s continued engagement with the regulated community as it considers revisions to the Proposition 65 regulations.

FCA is the principal fragrance trade association representing nearly 70 member companies that account for the majority of fragrance manufacturing in North America and span the fragrance value chain. Our members range from multinational manufacturers to small businesses and include companies that create, manufacture, and use fragrances and scents in home care, personal care, home design, fine fragrance, and industrial and institutional products. Our membership also includes suppliers of fragrance ingredients, including natural extracts and other raw materials used in perfumery and fragrance mixtures, collectively supporting innovation, safety, and economic growth across the fragrance value chain. Our members’ products are sold throughout California, and the proposed amendments would directly affect how those products are formulated, labeled, and marketed in the State.

FCA has a long record of constructive, science-based engagement with California agencies on questions of this kind, including comments to the California Air Resources Board on amendments to the Consumer Products Regulation, and with federal regulators, including technical work that the U.S. Environmental Protection Agency has recognized in its own review of new chemicals. We offer the comments below in that same spirit: to identify where the proposals

as drafted would create practical difficulties for regulated businesses without corresponding benefit to California consumers, and to suggest alternatives that better serve the statute's purpose of providing clear and reasonable warnings to California consumers, enabling them to make informed purchasing decisions.

The Proposed Amendment to Section 25501 Would Materially Alter the Naturally Occurring Framework and Create Significant Uncertainty for Naturally Derived Fragrance Materials

FCA appreciates OEHHA's interest in providing greater clarity regarding the scope of the naturally occurring exemption. The issue is particularly important to FCA's members because natural botanical materials are a significant part of the fragrance supply chain and impacts farmers and farming communities in California, the U.S., and around the world. Essential oils, extracts, absolutes, concentrates, isolates, and other botanical fragrance ingredients may contain listed constituents produced naturally by the source plant. Many of those botanical materials originate in plants that are also foods or food ingredients for purposes of Section 25501. Those materials necessarily undergo processing—including drying, pressing, distillation, extraction, concentration, fractionation, and related physical separation processes—before they can be used in fragrance applications. The central question is therefore not whether human activity was involved in processing the material, it is whether the listed chemical itself resulted from that human activity. Section 25501 has long provided the framework for determining whether and to what extent a listed constituent carried through those processes remains naturally occurring.

The proposed amendment would materially change the existing framework and the settled understanding of the naturally occurring regulation by making the act of extraction or concentration the potentially controlling factor even where the listed chemical itself was already present in the source material and remains chemically unchanged. The proposed language would introduce a processing-based consideration into a regulation that otherwise asks whether the chemical "resulted from" known human activity. In other words, the proposal shifts the naturally occurring inquiry away from the source of the listed chemical and toward the processing of the ingredient or product containing it. For naturally derived fragrance materials, that change is consequential: extraction, distillation, concentration, and related physical separation processes are often the means by which a naturally occurring constituent is recovered from the plant material, not processes that create or add the constituent.

That shift has substantial consequences for fragrances and is difficult to reconcile with the remainder of Section 25501. For the reasons discussed below, FCA respectfully requests that OEHHA withdraw the proposed amendment.

A. The Proposed Change to Section 25501

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 Abstracts Services Registry Number.

(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.

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

The starting point is the text and structure of Section 25501 itself. Proposition 65 requires a warning only where a business causes an “exposure” to a listed chemical, and Section 25501 specifies that human consumption of a food “shall not constitute an ‘exposure’” to the extent it can be established 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 one way 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 therefore expressly distinguishes between the naturally occurring portion and the portion attributable to human activity.

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 or food ingredient.

OEHHA’s Final Statement of Reasons confirms that distinction. Final Statement of Reasons, Article 5, §§ 12501-12504, California Health & Welfare Agency, June 1989, at 9 (available at oehha.ca.gov). In explaining the cultivation exception, the Agency stated that the carve-out “was intended to be a limited exception for basic cultivation practices which are not expected to increase the amount of chemicals in food.” The Agency thus focused on whether the human activity increased the amount of the listed chemical beyond what was naturally present—not merely on whether human activity occurred somewhere in the production process. That distinction is consistent with the text of subdivision (a)(3), which asks whether the chemical “resulted from” human activity.

Indeed, this was the distinction that the Court of Appeal relied on in rejecting a challenge to the naturally occurring regulation. See *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). The court further observed that, “[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.

Thus, the reasoning for the *Nicolle-Wagner* court’s decision supports distinguishing between human activity that causes or adds a listed chemical and human activity that merely processes a material in which the chemical already exists.

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.” This requirement for reduction of contaminant levels does not apply to the levels of constituents.

Finally, subdivision (b) expressly carries the same principle into non-food consumer products. Where a naturally occurring chemical in food enters another consumer product because that food is used in the “manufacture, production, or processing” of the product, the naturally occurring portion remains outside the definition of 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.

C. The Existing Framework Has Been Applied to Naturally Derived Constituents That Remain Present Following Processing

Although Section 25501 is framed principally around exposures to listed chemicals in food, the proposed interpretive principle would have consequences well beyond food products. Many of the constituents that occur naturally in food and plants are also constituents of fragrance ingredients and appear in personal-care, cosmetic, and household products alike. Whatever the formal scope of the amended provision, the interpretive principle OEHHA adopts here will not remain confined to the food context; private enforcers will invoke it in notices directed at fragrance ingredients and fragrance-containing consumer products.

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, extracting, blending, concentrating, or otherwise processing the botanical material—has been understood as changing the concentration of an already naturally occurring chemical, not as converting a naturally occurring chemical into one that “results from” human activity. 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 interpreting and upholding the regulation as consistent with Proposition 65, the letter treated the origin of the chemical—not the mere fact that human processing had separated it from its source—as the central consideration. 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. That conclusion is of direct rather than analogous significance to FCA's members: methyleugenol is a naturally occurring constituent of a range of botanical materials used in perfumery, including rose, basil, and bay oils.

That principle is particularly important to the fragrance industry. Botanical fragrance materials routinely undergo several stages of processing before they are incorporated into a finished fragrance or scented consumer product. Flowers, leaves, peels, woods, roots, resins, and other plant materials may be steam-distilled, cold-pressed, solvent-extracted, fractionated, rectified, concentrated, or otherwise processed to produce essential oils, absolutes, extracts, isolates, and related fragrance ingredients. Those materials may then be blended with other fragrance ingredients and incorporated into perfumes, cosmetics, personal-care products, household products, and numerous other consumer goods. In many instances, the processing does not create the naturally occurring constituent at issue; it merely separates, preserves, purifies, or concentrates a constituent that the plant itself produced.

Critically, concentration is not an optional step that a fragrance manufacturer elects to perform. It is the inherent and unavoidable consequence of separating a volatile aromatic fraction from bulk plant material. Essential oil production characteristically yields a small quantity of oil from a large quantity of botanical starting material. The resulting increase in the measured concentration of any given constituent reflects the removal of water and other non-volatile plant matter rather than the introduction of additional amounts of that constituent through human activity. This is true even of the simplest and most mechanical production methods: cold-pressed citrus oil is obtained by pressing the peel, with no solvent or heat, thereby separating the naturally occurring constituents already present in the plant material. Likewise, extraction, distillation, fractionation, and purification may separate, concentrate, or further purify a naturally occurring constituent, they do not chemically create or transform that constituent. The constituent remains the same naturally occurring chemical produced by the plant. A rule keyed to whether a material has been “concentrated” would therefore reach essentially every botanical fragrance ingredient in

commerce, without regard to whether human activity had any bearing on the presence of the listed chemical.

That broad reach also highlights an important practical distinction between naturally occurring constituents and contaminants. Unlike a contaminant, which can often be avoided through changes in sourcing or production, a naturally occurring constituent is inherent to the botanical material itself and cannot simply be removed or avoided without changing the nature of the material. Nor, in most cases, does a reformulation path exist. Where a listed chemical is present in food as a contaminant, a business can address this by changing suppliers, altering agricultural practices, or sourcing from a different growing region. A naturally occurring aromatic constituent presents a fundamentally different situation, because the constituent is not an impurity in the material but a component of what the material is. A business cannot remove a naturally occurring constituent from an essential oil and still have that essential oil; the chemistry that produces the constituent is the same chemistry that produces the scent. The practical alternatives available to a business are therefore to warn on natural botanical products, or to abandon naturally derived materials in favor of synthetic substitutes. Neither outcome advances the purposes of Proposition 65, and the second would fall hardest on the agricultural producers and small businesses that supply natural botanical materials—a substantial portion of the fragrance value chain that FCA represents.

The same concern exists in the food industry. Nearly every packaged food undergoes some form of processing, and processing may change the concentration of naturally present constituents by weight. Drying a grape to make a raisin, for example, removes water and thereby increases the concentration of naturally occurring sugars by weight, without adding or creating those sugars. The identical dynamic operates in the fragrance context: drying lavender flowers for use in sachets and potpourri removes water and increases the measured concentration of constituents the plant itself produced, even though no constituents have been added or chemically transformed. So too with distilling basil essential oil from basil leaves: the process separates and concentrates the constituents already present in the plant. In each case, the increased concentration results from the removal of water or separation from plant material, not from human activity causing the listed chemical to exist. The chemical was already present in the plant and remains the same chemical after processing.

For both food and fragrance products, the relevant distinction should therefore remain the one reflected in the existing regulation and OEHHA's historical interpretation: whether the listed chemical itself is present because of natural processes or because of human activity. Routine processing of a naturally occurring botanical constituent—without the creation or introduction of additional amounts of that constituent through human activity—should not eliminate the exemption merely because the constituent has been extracted, distilled, concentrated, isolated, or incorporated into another product.

D. 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. The proposed language would instead make the fact that a chemical has been extracted or

concentrated independently relevant, even where the chemical was already naturally present and remains chemically unchanged.

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”). Nothing in the regulation suggests that post-harvest processing, standing alone, constitutes disqualifying ‘human activity’ where the processing does not cause or introduce the listed chemical. As the contemporaneous rulemaking record confirms, the Agency instead distinguished between processing that merely carries a naturally occurring chemical forward and processing that causes the chemical to be present.

OEHHA’s new proposal would reverse this understanding and for the first time would consider common post-harvest food-processing techniques such as “extraction or concentration” as potentially disqualifying. Without a definition, the following ordinary food-processing steps could all potentially be 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 processes can increase the concentration of some chemicals (whether constituents or contaminants) in the finished product. The proposed language does not identify which processes are covered, whether the degree of concentration matters, or whether the purpose of the processing matters. Without such criteria, businesses cannot determine whether their products fall within or outside the regulation, and the proposed change provides 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 not 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—such as a fragrance or a personal care product containing a fragrance—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.

The original rulemaking record removes any doubt on this point. During the 1989 rulemaking, a commenter specifically requested an amendment clarifying that adding a food containing a naturally occurring chemical to another food would not constitute an exposure. The Agency declined to make the change—not because it disagreed, but because the requested clarification was unnecessary:

One comment recommended an amendment to clarify that addition of a food containing a naturally occurring chemical to another food does not constitute an “exposure.” . . . This amendment is not necessary because it is evident from the regulation as a whole that once a chemical is exempt as a naturally occurring chemical in food, the exempt status of that particular chemical will “carry over” to

any other food to which it is added. Subdivision (b) provides that this exempt status will even “carry over” to other consumer products.

Final Statement of Reasons, Article 5, §§ 12501-12504, California Health & Welfare Agency, June 1989, at 9.

The Agency separately explained subdivision (b) in equally direct terms: where consumption of a naturally occurring chemical in a food would not constitute an exposure under subdivision (a), “the same naturally occurring chemical will similarly not give rise to an ‘exposure’ if the food is subsequently used in the production or processing of a consumer product other than food.” The words “production or processing” are significant. The Agency expressly contemplated that a food containing the naturally occurring chemical could be processed into another consumer product without the processing itself destroying the chemical’s exempt status.

The rulemaking history therefore goes considerably further than the text of subdivision (b) standing alone. The Agency considered the precise question whether naturally occurring status follows a chemical as its source material is incorporated into something else and answered yes. Indeed, it declined to add clarifying language because that result was already “evident from the regulation as a whole.” That history makes it difficult to characterize as a mere clarification a proposal that would now permit extraction or concentration, standing alone, to defeat the carry-over principle the Agency said was already embedded in the regulation.

The Final Statement of Reasons also stated that “[s]ince chemicals in food which are caused by cooking, fermentation, or any other processing are added to the food by human agency, they are the result of known human activity and thus cannot be considered naturally occurring.” That statement does not establish that processing itself defeats naturally occurring status. It addresses a different circumstance: a listed chemical that is caused by the processing (a chemical that the processing creates or generates rather than one that was already present in the source material). The Agency’s choice of words matters. A chemical “caused by” cooking or fermentation results from the human activity; a constituent that the plant already synthesized does not become caused by human activity merely because it is later separated from the plant matrix and concentrated for use as a flavor or fragrance. The distinction is between processing that creates or introduces the listed chemical and processing that merely recovers, separates, or concentrates a chemical that was already present in the source material.

That distinction remains reflected in OEHHA’s treatment of processing-generated chemicals. Acrylamide, for example, is formed through cooking or heat processing and therefore presents the circumstance described in the Final Statement of Reasons: human processing generates the listed chemical itself. Extraction, pressing, distillation, milling, or drying of a constituent *already present* in the source material presents the opposite circumstance. Those processes may change the material surrounding the constituent or its concentration by weight, but they do not cause the constituent to exist.

Applied to botanical fragrance ingredients, that approach is both workable and consistent with the regulation’s text. A constituent synthesized by the plant does not cease to be naturally occurring merely because the botanical material is converted from a flower, leaf, peel, wood, or other plant material into an essential oil, absolute, extract, concentrate, or isolate. Those processing steps may alter the surrounding matrix, remove water or other plant matter, or increase

the constituent's concentration, but they do not change the source of the constituent itself. By contrast, if a manufacturer introduces additional quantities of the listed constituent—for example, by fortifying a botanical material with a synthetic or separately sourced counterpart—the added quantity is attributable to human activity and falls outside the exemption.

The existing regulation already accommodates that distinction. The proposed amendment would instead shift the inquiry toward the nature or degree of processing, even though processing does not answer the question Section 25501 has historically asked: whether the listed chemical itself results from human activity. This uncertainty is not academic. Fragrance ingredient suppliers, fragrance manufacturers, and manufacturers of fragrance-containing products must make compliance decisions across a wide range of botanical materials and production methods. The regulation should allow those businesses to determine whether drying lavender, expressing citrus peel, steam-distilling basil leaves, producing an absolute or extract, or fractionating a botanical oil changes the Proposition 65 treatment of a constituent the plant itself produced. The proposed language does not do so.

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For these reasons, FCA respectfully urges OEHHA to withdraw and not to proceed on the proposed change to Section 25501. We appreciate the opportunity to submit these comments on OEHHA's discussion draft and welcome further discussion of these proposals with OEHHA and other stakeholders.

Respectfully submitted,



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