Qalitex Labs Outlines EU Fragrance Allergen Labeling Rules Ahead of 2026 & 2028 Deadlines

IRVINE, CA, UNITED STATES, March 13, 2026 /EINPresswire.com/ -- ISO 17025-accredited testing laboratory explains the compliance steps U.S. cosmetic exporters need to take now as the European Union's expanded Annex III allergen list takes effect

Qalitex Laboratories, an ISO 17025-accredited third-party analytical testing laboratory serving cosmetic companies, dietary supplement brands, and consumer goods manufacturers across North America, today shared expert analysis on the European Union's expanded fragrance allergen labeling requirements — changes that will affect every U.S. cosmetic brand exporting fragrance-containing products to EU member states. The updated requirements, which amend Annex III of EU Cosmetics Regulation (EC) No. 1223/2009, introduce a significantly expanded list of fragrance allergens that must be individually disclosed on product labels when present above specified concentration thresholds. With the first compliance deadline of July 31, 2026 now less than five months away, cosmetic brands that have not yet begun their regulatory review may face formulation, labeling, and documentation challenges that take longer to resolve than the available window allows.

Background: What the EU Regulation Actually Requires
The EU Cosmetics Regulation (EC) No. 1223/2009 has governed cosmetic product safety and labeling across the European Union for over a decade. Annex III of that regulation specifies substances that cosmetic products may contain only subject to restrictions — including concentration limits and mandatory label disclosure requirements.

The recent amendment expands the number of fragrance allergens listed in Annex III and strengthens the labeling obligations associated with them. Under the revised framework, fragrance ingredients that were previously permitted to appear on labels under the collective term "parfum" or "fragrance" must now be individually identified when they are present above the applicable concentration threshold in the finished product.

The scientific basis for these changes comes from the European Commission's Scientific

Committee on Consumer Safety (SCCS), which has evaluated numerous fragrance compounds for their skin sensitization potential. The SCCS assessments identified a broader set of compounds associated with allergic contact dermatitis than were covered under the prior version of Annex III, prompting the regulatory expansion.

The updated requirements are being implemented through a phased timeline designed to give manufacturers time to reformulate, relabel, and update their regulatory documentation:

July 31, 2026 — All newly introduced cosmetic products placed on the EU market must comply with the expanded allergen labeling requirements.
July 31, 2028 — All existing cosmetic products already on the EU market must meet the new standards or be withdrawn from sale.
Expert Perspective: What This Means in Practice
"The compliance challenge here isn't just about adding ingredient names to a label," said Nour Abochama, Vice President of Operations at Qalitex Laboratories and co-host of the Nourify & Beautify podcast. "The brands we work with often discover that their fragrance suppliers have been providing them with IFRA certificates and safety data sheets that don't break out individual allergen concentrations at the level of specificity the EU now requires. Getting that data — and verifying it through testing rather than relying solely on supplier documentation — takes time. The brands that start this process now will be in a much better position than those who wait until Q1 2026 and realize their formulation documentation isn't sufficient for EU market entry."

The Three Compliance Areas Cosmetic Exporters Need to Address
For U.S. cosmetic and personal care companies selling into the European market, the expanded allergen list creates compliance obligations across three distinct areas: formulation review, labeling, and regulatory documentation.

Formulation Review and Potential Reformulation

The expanded Annex III list includes fragrance compounds that were previously unrestricted or subject only to general "parfum" disclosure. Brands whose current formulations contain these compounds above the applicable thresholds will need to evaluate whether to reformulate — replacing or reducing the concentration of the flagged ingredient — or accept the labeling obligation and ensure their documentation supports it.

In either case, the starting point is a complete fragrance allergen analysis of the finished product. Supplier-provided ingredient declarations are a useful starting point, but they are not a substitute for analytical testing when regulatory compliance is at stake. Concentration thresholds under Annex III apply to the finished product, not to the fragrance concentrate, which means dilution factors and final formulation concentrations must be verified.

Labeling Updates

When a regulated allergen is present above the applicable threshold — 0.001% (10 ppm) in rinse-off products and 0.0001% (1 ppm) in leave-on products under the general EU labeling framework — it must be listed individually on the product label by its INCI name, in addition to any collective "parfum" or "aroma" declaration.

For brands with established EU product lines, this means reviewing every SKU that contains a fragrance component, cross-referencing the ingredient list against the updated Annex III, and determining which products require label revisions. Brands with large portfolios should prioritize this audit now, as label redesign, print lead times, and EU responsible person notifications add weeks to the compliance timeline.

Regulatory Documentation

EU cosmetic products must be supported by a Product Information File (PIF) that includes a cosmetic product safety report (CPSR) signed by a qualified safety assessor. The CPSR must reflect the updated allergen status of the formulation. For products that require reformulation or labeling changes, the CPSR will need to be updated before the product can be legally placed on the EU market under the new requirements.

U.S. exporters who sell through EU-based distributors or retailers should confirm with their EU responsible person — the entity legally designated to maintain the PIF and ensure compliance — that the documentation update process is underway.

Industry Context: Why This Regulation Matters Beyond the EU
"What we see in our work with cosmetic brands is that the EU's regulatory framework tends to set a benchmark that other markets eventually move toward," Abochama noted. "Brands that build their compliance documentation to EU standards often find that meeting other market requirements — Health Canada's cosmetic notification requirements, for example, or California's stricter ingredient disclosure rules — becomes more straightforward. The investment in getting EU-compliant documentation right has downstream value across the brand's entire regulatory posture."

The EU has historically maintained more prescriptive cosmetic ingredient regulations than the United States, where the FDA's authority over cosmetic labeling has been more limited. The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) has begun to shift that dynamic in the U.S. market, introducing new fragrance allergen disclosure requirements for certain product categories. Brands preparing for EU compliance will find that much of the documentation work overlaps with MoCRA's fragrance transparency provisions.

For cosmetic brands with global distribution ambitions, the practical implication is that fragrance allergen documentation is no longer a niche regulatory concern — it is a baseline requirement for market access in the EU and an increasingly relevant standard in other jurisdictions.

Preparing for the Transition: A Practical Timeline

Given the July 31, 2026 deadline for new product introductions, cosmetic brands that have not yet begun their compliance review should consider the following sequence:

Fragrance allergen audit — Obtain full fragrance ingredient disclosure from all fragrance suppliers, including individual compound concentrations. Where supplier data is incomplete, commission analytical testing of the finished product.

Annex III cross-reference — Compare the fragrance ingredient list against the updated Annex III to identify which compounds require individual label disclosure.

Threshold verification — Confirm finished-product concentrations through analytical testing for any compounds near or above the applicable thresholds.

Label revision — Update EU-market labels to include required allergen disclosures. Notify the EU responsible person of label changes.

CPSR update — Work with the EU safety assessor to update the cosmetic product safety report to reflect the current formulation and allergen status.

PIF maintenance — Ensure the Product Information File is complete and current before the product is placed on the EU market.

Brands with existing EU market presence face the additional task of auditing their current product portfolio against the expanded allergen list before the July 31, 2028 deadline for existing products.

Resources

EU Cosmetics Regulation (EC) No. 1223/2009 — EUR-Lex official text

European Commission SCCS opinions on fragrance allergens — available at ec.europa.eu/health/scientific_committees/consumer_safety

Cosmetic brands with questions about fragrance allergen testing or EU compliance documentation may contact Qalitex Laboratories at nour@qalitex.com

About Qalitex Laboratories

Qalitex Laboratories is an ISO 17025-accredited third-party analytical testing laboratory with facilities in Irvine and San Diego, California. The laboratory provides certificate of analysis (COA) testing, heavy metal analysis by ICP-MS, microbiology testing per USP <61> and <62>, preservative efficacy testing (PET), cosmetic stability studies under ICH guidelines, fragrance allergen analysis, and regulatory compliance support for cosmetic companies, dietary supplement brands, and consumer goods manufacturers.

Qalitex serves brands at every stage of the product lifecycle — from raw material incoming inspection through finished product release testing — with turnaround times starting at 48 hours for standard panels. The laboratory's testing programs are designed to meet the requirements of 21 CFR Part 111, California Proposition 65, Amazon's supplement and cosmetic compliance requirements, EU Cosmetics Regulation (EC) No. 1223/2009, and Health Canada's cosmetic notification framework.

Nour Abochama, VP of Operations at Qalitex, also co-hosts the Nourify & Beautify podcast, a

consumer education series covering supplement safety, skincare science, and cosmetic ingredient transparency.

For testing inquiries, contact Qalitex Laboratories at nour@qalitex.com or visit https://qalitex.com.

Nour Abochama
Qalitex Laboratories
+1 858-231-2994
email us here
Visit us on social media:
LinkedIn
Instagram
Facebook
