Ingenious Brain

Future-Proofing Businesses

Navigating EU Cosmetic Ingredients Regulations:

Insights and Strategies for Compliance and Innovation

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Introduction

The European Union (EU) is a global leader in regulating cosmetic ingredients, ensuring consumer safety and environmental sustainability through a robust framework. The cornerstone of this framework, Regulation (EC) No 1223/2009, mandates stringent safety assessments, bans over 1,600 substances, and restricts others to protect human health and the environment. Recent updates, such as Regulation (EU) 2024/996, effective from April 23, 2024, introduce new restrictions on ingredients like Vitamin A derivatives, Triclosan, Triclocarban, Alpha-Arbutin, Genistein, Daidzein, Kojic Acid, and 4-Methylbenzylidene Camphor (4-MBC). Additionally, proposed bans on Per- and Polyfluoroalkyl Substances (PFAS) and microplastics signal a shift toward sustainable formulations, driven by the EU's 2020 Chemicals Strategy for Sustainability (CSS) under the EU Green Deal.

These regulatory changes pose significant challenges for the cosmetic industry, requiring reformulation of products to comply with new limits while maintaining efficacy and consumer appeal. However, they also present exciting opportunities for innovation, particularly in the growing natural and eco-friendly cosmetics market, projected to reach USD 59 billion by 2031. Ingenious e-Brain, a global consulting firm specializing in techno-commercial and strategy consulting, provides critical insights to navigate these changes. Their forecasts highlight alternative ingredients like Bakuchiol and SymGuard CD as high-potential replacements for restricted substances, enabling companies to align with regulatory and consumer demands. This whitepaper explores the EU's regulatory landscape, the impact of ingredient restrictions, and strategic approaches for compliance, emphasizing Ingenious e-Brain's analytical insights to guide the cosmetic industry toward a sustainable and innovative future.

EU Cosmetic Regulations: A Comprehensive Overview

The EU's cosmetic regulatory framework is primarily governed by Regulation (EC) No 1223/2009, effective since July 2013, harmonizing standards across all 27 member states. This regulation ensures that cosmetic products are safe for human use, properly labeled, and compliant with environmental standards. Key components include:

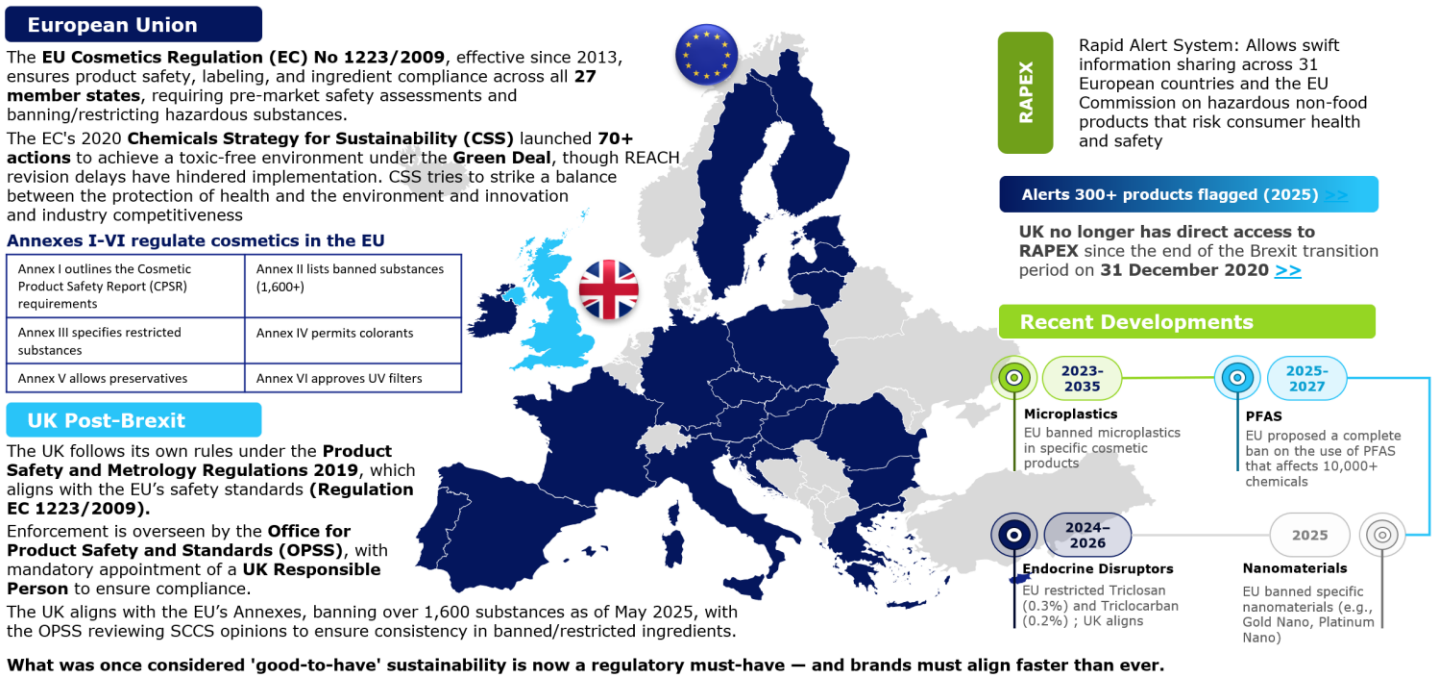
- **Pre-Market Safety Assessments**: Manufacturers must conduct a Cosmetic Product Safety Report (CPSR) to evaluate product safety before market entry.
- **Annexes for Ingredient Control**: Annex II lists over 1,600 banned substances, Annex III specifies restricted substances with usage limits, Annex IV permits colorants, and Annex V allows preservatives under defined conditions.
- **Labeling Requirements**: Products must display ingredient lists, warnings, and contact details of the Responsible Person in the EU.

The introduction of Regulation (EU) 2024/996 builds on this framework, introducing specific restrictions based on scientific opinions from the Scientific Committee on Consumer Safety (SCCS) and the Scientific Advisory Group on Chemical Safety (SAG-CS). These bodies assess ingredients for potential health and environmental risks, driving regulatory updates. The regulation targets ingredients with known or suspected risks, such as endocrine disruptors and environmentally persistent substances, with transition periods to allow industry adaptation (e.g., December 2024 to May 2027).

The EU's 2020 Chemicals Strategy for Sustainability (CSS), part of the EU Green Deal, further shapes the regulatory landscape by aiming for a toxic-free environment. Over 70 actions under the CSS address hazardous chemicals, with delays in implementation due to ongoing revisions to the Registration, Evaluation, Authorisation, and Restriction of Chemicals

(REACH) framework. Proposed bans on PFAS and microplastics, driven by NGOs like the European Environmental Bureau (EEB) and Health and Environment Alliance (HEAL), reflect this commitment to sustainability.

Post-Brexit, the UK aligns closely with EU standards under the Product Safety and Metrology Regulations 2019, enforced by the Office for Product Safety and Standards (OPSS). By May 2025, over 1,600 substances will be banned in the UK, consistent with EU Annexes, requiring a UK Responsible Person for compliance.



Impact of Regulatory Changes on the Cosmetic Industry

The tightened regulations under Regulation (EU) 2024/996 and proposed bans on PFAS and microplastics present both challenges and opportunities. Reformulating products to comply with new restrictions involves significant costs, research, and development efforts. For instance, restrictions on Vitamin A derivatives impact anti-aging products, a key market segment, while bans on Triclosan and Triclocarban require new antimicrobial solutions. PFAS and microplastic restrictions demand alternatives for functional properties like water resistance and exfoliation, which are critical to product performance.

However, these changes align with consumer trends toward clean, natural, and sustainable cosmetics. The global cosmetic ingredients market is projected to grow from USD 35.5 billion in 2024 to USD 61.2 billion by 2033, with a compound annual growth rate (CAGR) of 6.2%. The clean beauty market, a subset of this, is expected to reach USD 11.6 billion by 2027, growing at a CAGR of 12.07%. Consumer surveys indicate that 65% of consumers prioritize environmentally friendly brands, and 55% are willing to pay more for sustainable products, creating a strong market incentive for compliance and innovation.

Detailed Analysis of Banned and Restricted Ingredients

1. Vitamin A Derivatives (Retinol, Retinyl Acetate, Retinyl Palmitate)

Background and Uses: Vitamin A derivatives are cornerstone ingredients in anti-aging skincare, valued for promoting cell turnover, boosting collagen production, and improving skin elasticity. Retinol, in particular, is a gold-standard ingredient for reducing fine lines, wrinkles, and hyperpigmentation, widely used in serums, creams, and lotions.

Reasons for Restriction: The SCCS identified potential developmental toxicity risks when exposure to Vitamin A from cosmetics, food, and supplements exceeds safe intake levels, affecting approximately 5% of the population, particularly pregnant women. This led to restrictions to minimize health risks while balancing the ingredients' benefits.

Regulatory Details: Under Regulation (EU) 2024/996, Vitamin A derivatives are limited to 0.05% Retinol Equivalent (RE) in body lotions and 0.3% RE in other leave-on and rinse-off products. Products must carry a warning label: "Contains Vitamin A. Consider your daily intake before use." Compliance deadlines are November 1, 2025, for new products and May 1, 2027, for existing products.

2. Triclosan and Triclocarban

Background and Uses: Triclosan and Triclocarban are antimicrobial agents used in soaps, deodorants, toothpastes, and oral care products to prevent bacterial growth and ensure product stability. Their broad-spectrum antimicrobial properties make them effective in personal care applications.

Reasons for Restriction: Both ingredients are classified as endocrine disruptors, potentially interfering with thyroid function and reproduction. Triclosan is linked to antimicrobial resistance and environmental persistence, accumulating in water bodies and wildlife. Triclocarban amplifies hormone effects, raising similar concerns.

Regulatory Details: The regulation restricts Triclosan to 0.3% in toothpastes, hand soaps, body soaps, deodorants, face powders, and blemish concealers, and 0.2% in mouthwashes. Triclocarban is limited to 0.2% in all cosmetic products except mouthwash. Compliance deadlines are December 31, 2024, for new products and October 31, 2025, for existing products.

3. Alpha-Arbutin, Arbutin, Genistein, Daidzein, Kojic Acid, and 4-MBC

Background and Uses:

- **Alpha-Arbutin and Arbutin**: Used for skin lightening to reduce hyperpigmentation and dark spots.
- **Genistein and Daidzein**: Phytoestrogens used in anti-aging products for their antioxidant properties.
- **Kojic Acid**: A skin-lightening agent derived from fungi that treats melasma and age spots.
- **4-Methylbenzylidene Camphor (4-MBC)**: A UV filter in sunscreens for UV-B protection.

Reasons for Restriction:

- **Alpha-Arbutin and Arbutin**: Restricted due to potential hydroquinone release, a known carcinogen.
- **Genistein and Daidzein**: Suspected endocrine disruptors, potentially affecting hormonal balance.
- **Kojic Acid**: Concerns over mutagenicity and potential liver toxicity.

- **4-MBC**: Identified as an endocrine disruptor with environmental persistence.

Regulatory Details: Specific concentration limits and compliance deadlines vary, with transition periods aligned with those for other restricted ingredients (2024–2027).

4. Per- and Polyfluoroalkyl Substances (PFAS)

Background and Uses: PFAS are used as emulsifiers, stabilizers, and film-forming agents in cosmetics like foundations, sunscreens, and mascaras, valued for their water- and oil-repellent properties.

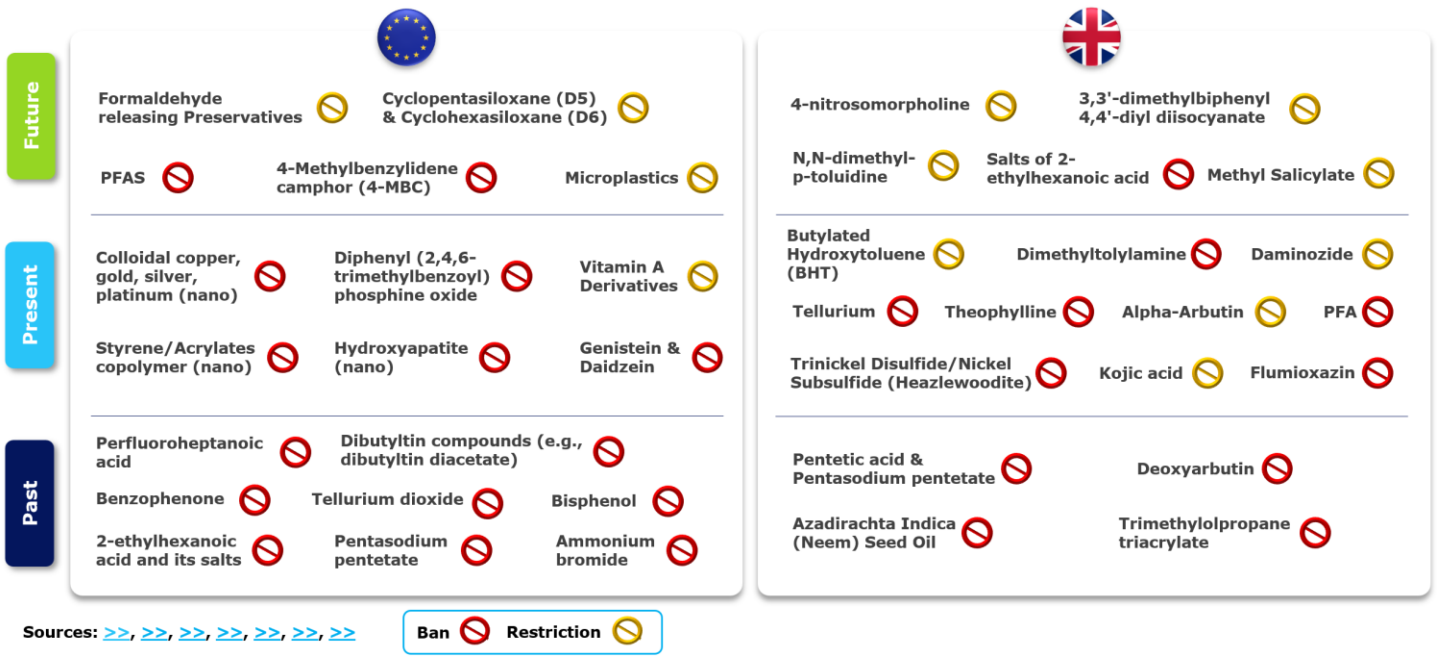
Reasons for Proposed Ban: Known as "forever chemicals," PFAS persist in the environment and are linked to health risks, including cancer, hormonal disruption, and immunotoxicity. The Ban PFAS Manifesto, supported by over 100 NGOs, calls for a phase-out in consumer products by 2025 and production by 2030.

Regulatory Status: A 2023 proposal by five EU countries under the European Chemicals Agency (ECHA) aims to restrict approximately 10,000 PFAS. France has implemented a national ban on PFAS in cosmetics effective February 20, 2025, setting a precedent for EU-wide action.

5. Microplastics

Background and Uses: Microplastics, such as microbeads, are used as exfoliants, thickeners, and glitters in cosmetics, contributing to product texture and appearance.

Reasons for Restriction: Microplastics do not biodegrade, polluting ecosystems and entering food chains. Regulation (EU) 2023/2055 bans synthetic polymer microparticles in cosmetics if their concentration exceeds 0.01% by weight, with transition periods of 6–12 years for leave-on products like lipsticks.



Ingenious e-Brain's Insights on Alternative Ingredients

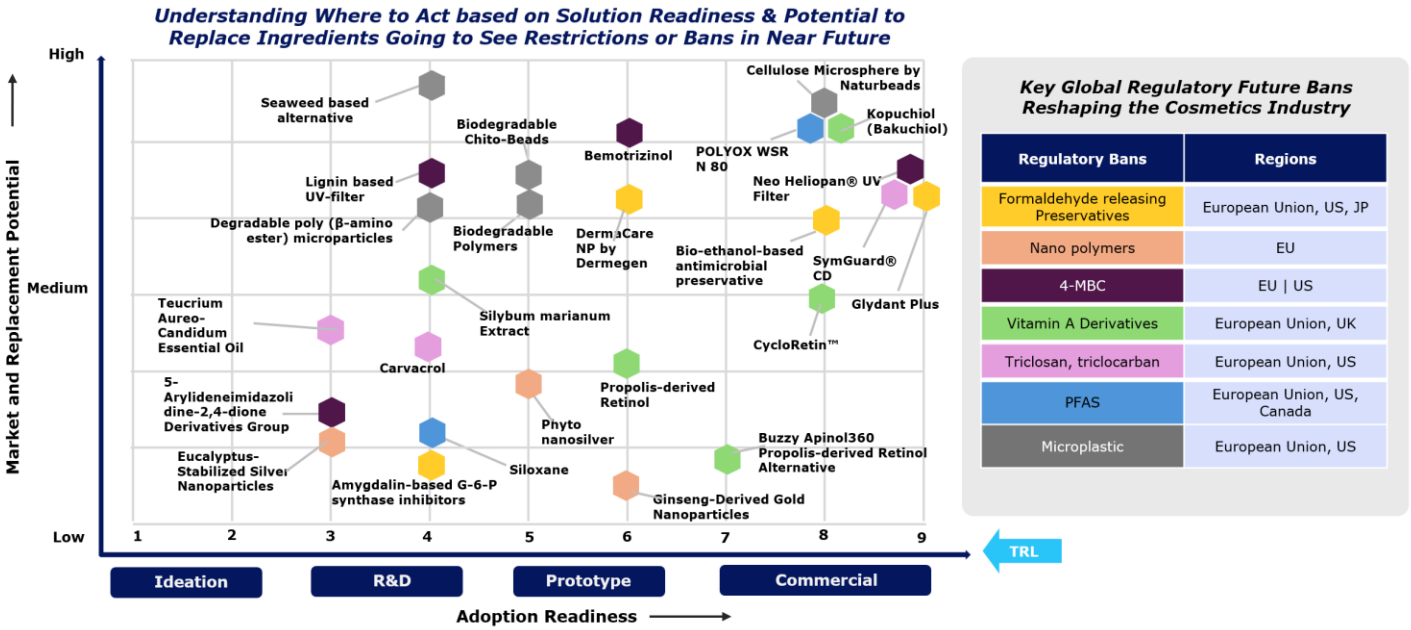
Ingenious e-Brain provides a strategic framework, "Regulatory Innovation Catalyst," for identifying and adopting alternative ingredients, ensuring compliance and market competitiveness. Their forecasts highlight specific replacements for restricted ingredients, supported by a robust evaluation methodology.

Ingenious e-Brain's Evaluation Framework – Regulatory Innovation Catalyst

Ingenious e-Brain employs a comprehensive framework to assess alternative ingredients, focusing on five key criteria:

Criterion	Description	Implication
Market Potential	Alignment with consumer preferences and market trends.	High potential ensures consumer acceptance and market growth.
Cost	Economic feasibility compared to other alternatives.	High costs may limit adoption unless offset by significant benefits.
Availability	Supply chain reliability and scalability.	Low availability hinders large-scale adoption.
Adoption	Industry and consumer interest in the alternative.	Low adoption delays compliance and market penetration.
Functional Overlap	Ability to replicate the performance of the banned ingredient.	Poor overlap complicates substitution unless other advantages are compelling.

This framework ensures that replacements like Bakuchiol and SymGuard CD are practical, compliant, and marketable. Ingenious e-Brain also recommends exploring other substitutes, such as Ethylhexylglycerin for parabens and bio-ethanol-based preservatives, to address additional regulatory restrictions.



Note: *Market and replacement potential depends on cost of alternative, availability, adoption, and overlapping potential of alternatives. Click on the hexagons to navigate through the respective solution.*

1. Bakuchiol for Vitamin A Derivatives

Source and Extraction: Bakuchiol, derived from the seeds of the Psoralea corylifolia (Babchi) plant, is extracted using monomolecular techniques to achieve high purity (>99%), eliminating residual solvents and psoralens. This ensures a clean, safe ingredient suitable for cosmetic applications.

Benefits:

- **Efficacy**: A 2018 study published in the British Journal of Dermatology found Bakuchiol to be as effective as Retinol in reducing wrinkles and hyperpigmentation, with significant improvements in skin elasticity and firmness at concentrations of 0.5–2.14%.
- **Safety**: Unlike Retinol, Bakuchiol is photostable, non-irritating, and suitable for sensitive skin, making it ideal for daytime use and clean beauty formulations.
- **Sustainability**: Its plant-based origin aligns with consumer demand for natural and eco-friendly products, with 68% of consumers seeking “clean” products and 59% preferring “natural and organic” formulations.

Market Potential: Bakuchiol’s alignment with the clean beauty trend positions it as a high-potential replacement. Its adoption is growing among brands targeting eco-conscious and sensitive-skin consumers, with market projections indicating strong growth in the anti-aging segment.

2. SymGuard CD for Triclosan and Triclocarban

Features: Developed by Symrise, SymGuard CD is a multifunctional, non-organohalogen ingredient offering fast-acting antimicrobial protection against gram-negative bacteria like E. coli and P. aeruginosa. It also functions as an antioxidant

and deodorant, effective against oral malodor. Its colorless, low-odor, and easy-to-process nature makes it versatile for soaps, oral care products, and deodorants.

Benefits:

- **Safety**: Avoids endocrine-disrupting effects and antimicrobial resistance associated with Triclosan and Triclocarban.
- **Sustainability**: Readily biodegradable, SymGuard CD addresses environmental concerns, earning the BSB Innovation Prize in 2018 for its eco-friendly profile.
- **Performance**: Effective at low concentrations, ensuring product stability and consumer safety across various applications.

Market Potential: SymGuard CD's multifunctionality and sustainability make it highly adoptable, particularly as 65% of consumers prioritize environmentally friendly products. Its recognition by industry awards enhances its appeal in the natural cosmetics market.

3. Emerging Alternatives for PFAS and Microplastics

PFAS Replacements: Specific replacements for PFAS are still under development due to their unique water- and oil-repellent properties. The industry is exploring silicone-based emulsifiers, natural oils, and bio-based polymers, but challenges remain in achieving functional equivalence. Ingenious e-Brain suggests that viable replacements must balance performance, cost, and market readiness.

Microplastic Replacements: Natural exfoliants like Cellulose Microspheres, ground almonds, and sugar are gaining traction as biodegradable alternatives to microplastics. These align with the EU's zero-pollution goals and consumer demand for sustainable products.

Ingredient	Trends	Reason for Restriction/Ban	Regions	Label Warning	Transition Period
Formaldehyde releasing Preservatives	Helps to prevent microbial growth >>	Formaldehyde is a known human carcinogen, and its slow-releasing preservatives pose health risks even at very low levels >>	EU, UK	Threshold for labeling to 0.001% (10 ppm)	July 2022-July 2026
Nano polymers (styrene/acrylates copolymer, sodium styrene /acrylates copolymer)	Used as colorants, UV filters, or preservatives >>	Potential skin penetration and toxicity risks, with insufficient safety data >>	EU	Complete ban for use as colorants, UV filters, or preservatives	February-November 2025
4-Methylbenzylidene camphor (4-MBC)	A UV filter used to protect skin from UV radiation >>	Potential endocrine-disrupting properties and genotoxicity potential posing health risks >>	EU	Complete ban	May 2025-May 2026
Vitamin A Derivatives	Used for anti-aging, skin conditioning and other benefits >>	Risk of overexposure leading to developmental toxicity >>	EU	0.05% RE in body lotions, 0.3% RE in other products	November 2025-May 2027
Triclosan, Triclocarban	Antimicrobial preservatives to prevent bacterial growth >>	Endocrine disrupting and carcinogenic potential, Bioaccumulation, and potential risk for human health >>	EU	Triclosan is limited to 0.3%; triclocarban is restricted to 0.2%	December 2024-October 2025
Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)	Human-made chemicals for conditioning and texture >>	PFAS pose risks of persistence, bioaccumulation, and breakdown into smaller, potentially more toxic compounds >>	EU	Complete ban	EU: July 2025-Jan 2027 France: 1 Jan 2026
Microplastic	Tiny plastic particles (<5 mm) added to cosmetics as emulsifiers or low-cost fillers >>	Environmental persistence, potential cytotoxicity, and entire ecosystem harm >>	EU, UK	EU: SPM (<5mm) in glitter, facial scrubs & other types of cosmetics UK: banned microbeads in rinse-off products	EU: 2023-2035 UK: 2018

Legends | Details | Label Warning Required

Strategic Approaches for Compliance and Innovation

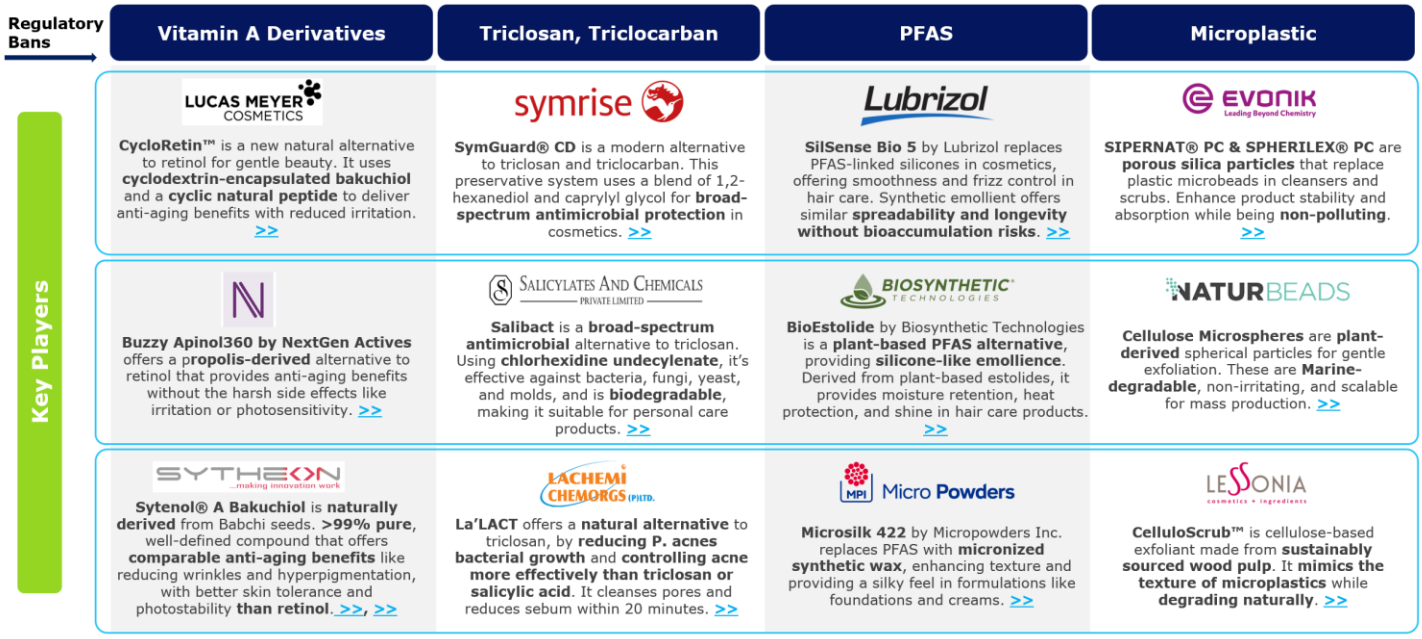
To navigate the evolving regulatory landscape, cosmetic companies should adopt the following strategies:

1. **Pre-Screening Ingredients**: Utilize toxicological databases and compliance tools to identify potential risks early in product development, reducing reformulation costs and delays.
2. **Proactive Reformulation**: Begin reformulating products ahead of compliance deadlines (e.g., 2024–2027) to maintain market presence and consumer trust. For example, incorporating Bakuchiol into anti-aging products requires testing to ensure its efficacy matches that of Retinol.
3. **Supplier Partnerships**: Collaborate with suppliers offering sustainable, compliant ingredients like SymGuard CD and Cellulose Microspheres to ensure a reliable supply chain.
4. **Consumer Education**: Transparently communicate the benefits of new formulations, emphasizing safety, efficacy, and sustainability to build consumer trust. For instance, marketing Bakuchiol as a "natural Retinol" can appeal to eco-conscious consumers.
5. **Regulatory Monitoring**: Stay informed about upcoming regulations and NGO activities, such as the Ban PFAS Manifesto, to anticipate future restrictions and develop substitution roadmaps.
6. **Sustainability Focus**: Align with consumer trends by prioritizing natural and eco-friendly ingredients, as evidenced by the projected growth of the natural cosmetics market to USD 59 billion by 2031.

Leading Companies and Innovations Leading to a Sustainable Future

Several companies are pioneering sustainable ingredients to meet regulatory and consumer demands:

- **BASF**: Develops ingredients supporting skin and hair health with a focus on sustainability, such as bio-based emollients and natural actives.
- **Croda**: Launched NatraFusion™ SL HA, a biosurfactant from renewable feedstocks, and ChromaPur™ CV2, an upcycled ingredient from black spruce, reducing waste and environmental impact.
- **Symrise**: Offers SymReboot™ L19 and SymLite® G8, produced using eco-friendly methods, and SymGuard CD, recognized for its sustainability.
- **Evonik**: Leverages biotechnology to create biosurfactants and vegan collagen, reducing environmental impact by up to 50% compared to traditional ingredients.
- **Evolved by Nature**: Produces Activated Silk™ peptides from upcycled resources, offering a sustainable alternative for skin hydration and protection.
- **Sparxell**: Develops plant-based color pigments, replacing synthetic dyes and microplastics in cosmetics.



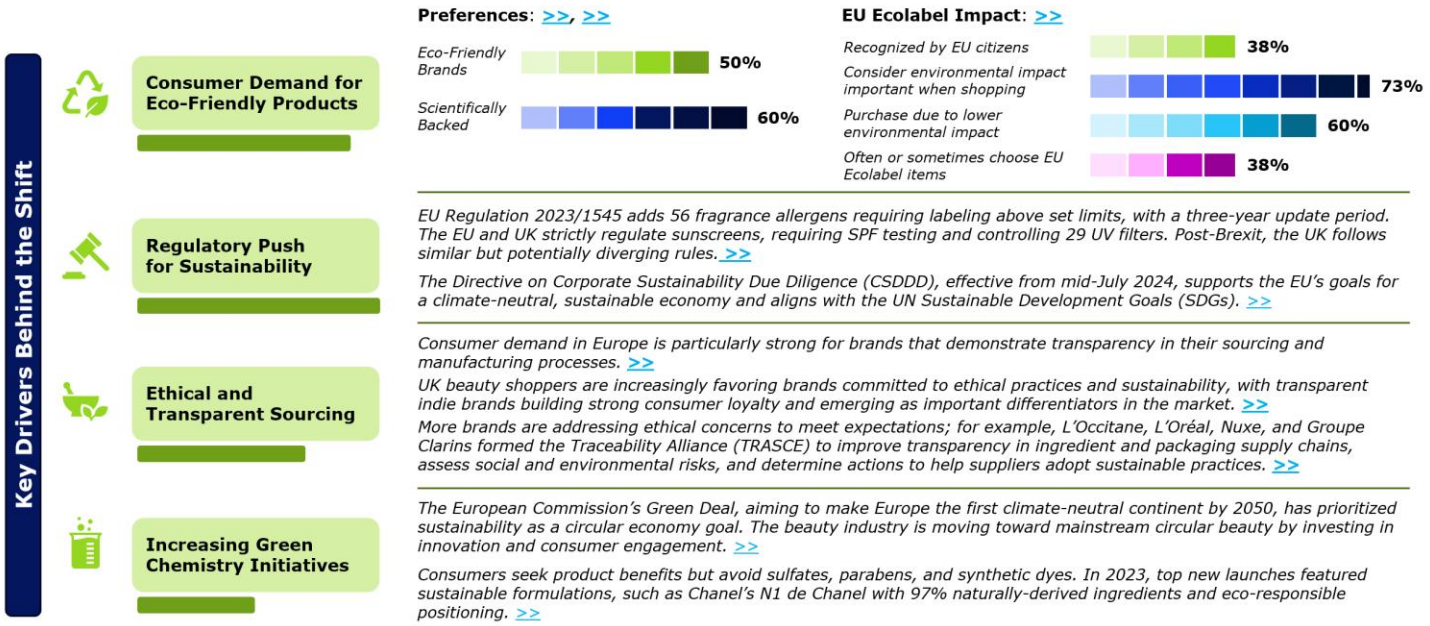
How Cosmetics Companies are Committed to the Green Goal

- **L'Oréal's Sustainability Commitment**: L'Oréal has pledged to make 95% of its ingredients bio-based by 2030. By replacing synthetic preservatives with natural alternatives like bio-ethanol-based preservatives in their skincare lines, L'Oréal has enhanced its sustainability profile while maintaining product efficacy. This shift has strengthened consumer trust, with a 15% increase in sales of eco-friendly product lines reported in 2024.

- **The Body Shop's Microbead Ban**: In 2016, The Body Shop eliminated microbeads from its exfoliating products, replacing them with natural exfoliants like ground almonds and sugar. This proactive move anticipated Regulation (EU) 2023/2055 and boosted brand loyalty, with a 20% increase in sales of sustainable products by 2020.
- **Unilever's Clean Beauty Initiative**: Unilever reformulated its Dove skincare line to exclude PFAS and incorporate silicone-based emulsifiers, aligning with proposed EU bans. This transition increased market share by 10% in the EU clean beauty segment in 2023.

Consumer Trends

Consumer preferences are shifting toward transparency and sustainability. According to a recent survey by Ingenious e-Brain, 68% of EU consumers prefer brands with transparent ingredient sourcing, and 59% prioritize vegan and cruelty-free products. Biotechnology is also gaining traction, with lab-grown ingredients like vegan collagen and fermented extracts offering high purity and reduced environmental impact.

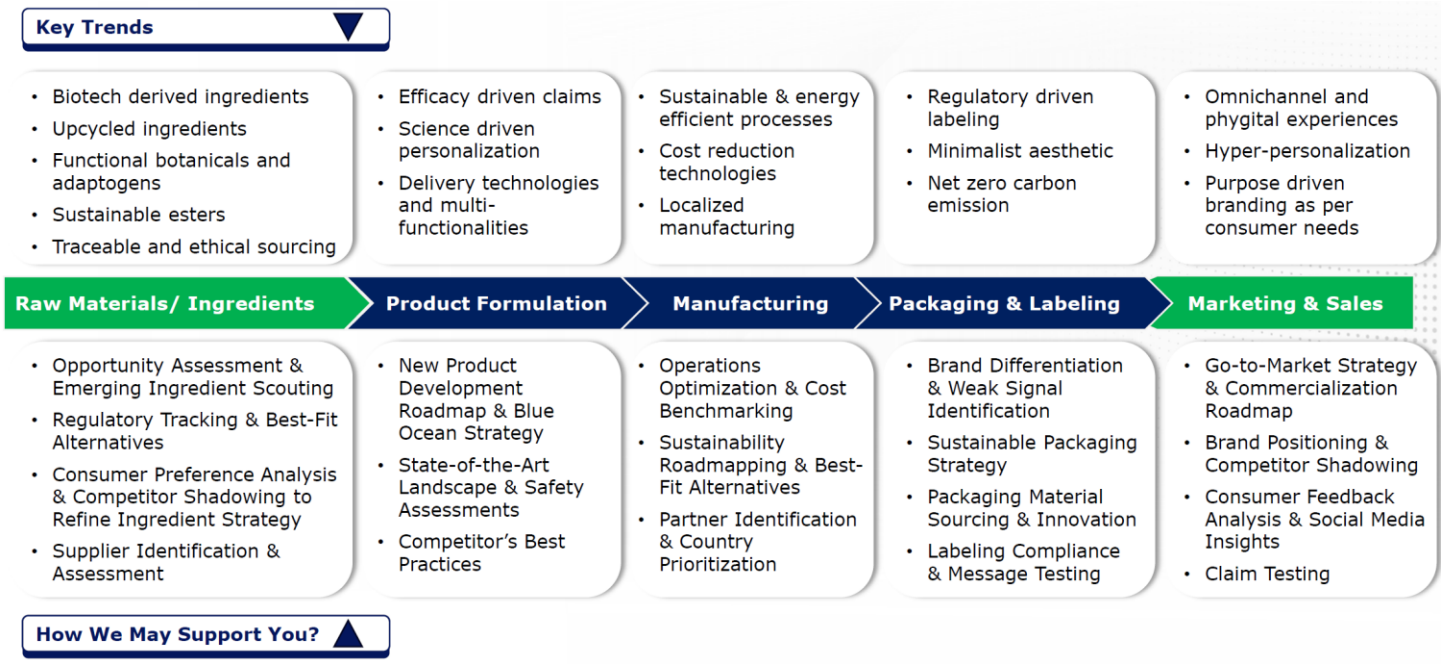


Note: *The dark green bar beneath each driver represents the relative strength or impact of that driver in influencing the shift toward sustainable beauty formulations.*

Global Implications of EU Regulations

While the EU leads in cosmetic regulation, its standards influence global markets. The US, for instance, is under pressure to align with EU bans on PFAS and microplastics, with states like California implementing similar restrictions. In Asia, countries like South Korea and Japan are adopting stricter ingredient standards, driven by consumer demand and trade with the EU. Ingenious e-Brain's insights are particularly valuable for multinational companies navigating these diverse regulatory landscapes, ensuring compliance across regions while capitalizing on the global clean beauty trend.

Ingenious e-Brain's Strategic Consulting Services Across the Value Chain



Conclusion

The EU's stringent cosmetic regulations, including Regulation (EU) 2024/996 and proposed bans on PFAS and microplastics, are reshaping the cosmetic industry. By leveraging Ingenious e-Brain's insights, companies can adopt high-potential alternatives like Bakuchiol, SymGuard CD, and natural exfoliants to achieve compliance and meet consumer demand for sustainable products. Proactive strategies, including reformulation, supplier partnerships, and consumer education, will ensure competitiveness in a market projected to reach USD 61.2 billion by 2033. As regulatory and consumer pressures converge, companies that embrace innovation and sustainability will lead the way in the evolving landscape of clean beauty.

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