Unlocking Regulatory Pathways for Novel Bio-Based Chemicals and Materials in the UK

BBIA

CHAMPIONING THE INDUSTRIAL BIOECONOMY

Contents

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Executive Summary

The *UK's Modern Industrial Strategy*[1] envisions the nation as one of the world's top three hubs for technology driven innovation by 2035, anchored by the ambition to create the UK's first trillion-dollar tech company.

Engineering Biology — the cornerstone of this new industrial era and one of the Industrial Strategy's 8 growth-driving sectors (IS-8)[2] — drives the sustainable design and manufacture of fuels, chemicals, materials, food, and medicines. Globally valued at over £30 trillion by 2050[3], the bioeconomy represents a transformative opportunity for the UK. The government has already committed £2 billion over the next decade, including £380 million for research, development, and infrastructure to scale bio-based products[4].

However, despite strong policy intent, the UK's regulatory framework for the bio-based sector remains outdated, fragmented, and at odds with innovation[5]. Current systems are historically structured around fossil-based inputs, creating unnecessary delays and ambiguity for novel bio-based chemicals and materials. These inefficiencies discourage investment, hinder SME competitiveness, and risk the UK falling behind global leaders such as the US, EU, and Singapore — countries actively modernising their regulatory systems to promote bio-based innovation[6].

To be successful, companies need three practical things from regulators (1) Predictable timelines and decision rules (2) Proportionate risk-based data requirements (3) Market incentives or procurement channels that reward sustainability.

Independent BBIA[7],[8] research and stakeholder consultation confirm that the UK's current policy and legislative frameworks fall far short of enabling bio-based producers to meet national sustainability and economic growth goals across all 3 requirements.

This report highlights that current UK regulatory complexity is the second-largest barrier to commercialisation of bio-based innovation. For the UK cosmetics ingredients sector, this equates to approval times for bio-based ingredients taking up to 45% longer, and costing more than double, than those for their fossil-derived equivalents.

For just 3 UK-based SMEs the nation is losing £35.7 million in annual GVA—and over 473 potential jobs[9] remain unrealised, representing a significant and avoidable economic drain. With hundreds of similar bio-based SMEs in the UK, the actual annual loss could easily be estimated to be well into the tens of billions.

To secure the UK's global leadership in engineering biology and sustainable innovation, decisive action is needed to establish a clear, proportionate, and science-led regulatory environment for bio-based chemicals and materials.

[1] The UK's Modern Industrial Strategy
[2] Industrial Strategy Sector Definitions List - GOV.UK
[3] TheGlobalBioeconomy
[4] assets.publishing.service.gov.uk/media/6892104df15b237bf6610996/industrial_strategy_digital_and_technologies_sector_plan_accessible.pdf
[5] BBREGNET_Addressing-the-UKs-polysemous-bioeconomy-_A-call-for-policy-cohesion.pdf
[6] From Research to Revenue: The Case for Scaling UK Bio-based
[7] www.bbia.org.uk
[8] Resource Hub - BB-REG-NET
[9] BBIA, unpublished, 2025

Key findings:

- Regulatory approval for a novel fossil-based cosmetic ingredient involves 7 stages, while a novel bio-based cosmetic ingredient requires 11 stages.
- On average, approval for a novel fossil-based ingredient takes around 50 weeks, compared to 72 weeks for a bio-based ingredient.
- Due to the increased complexity and additional regulatory requirements, the cost of approval for a bio-based cosmetic ingredient is more than double that of a fossil-based one — approximately £815,000 versus £372,000.

Key Recommendations

	Recommendation	Purpose	Actions	Lead(s)	Feasibility	Benefit
1	**Utilise Engineering Biology Sandbox Funding to test cross-sector solutions**	Foster coherent, innovation-friendly regulation across chemical and cosmetic, frameworks. Provide a unified, forward-looking framework for sustainable chemical innovation.	Establish a UK Bio-Based Materials Regulatory Roadmap (2026–2030) Define cross-sector alignment goals, pilot fast-track pathways and set clear service-level agreements for approvals. Develop a single-window submission portal for cross-agency coordination.	Defra / DBT / DSIT / FSA (via Coordination Taskforce)	**High**	**High**
2	**Create a Green Innovation Pathway**	Fast-track approvals for low-risk, sustainable, bio-based substances within UK REACH and OPSS frameworks.	Develop proportionate, risk-based routes for low-toxicity materials. Integrate sustainability-linked approval pilots that use lifecycle and circularity data. Consider how this can also transpose to other regulators, e.g. FSA for novel bio-based food contact materials.	Lead: HSE / OPSS /FSA	**Medium**	**High**
3	**Enable Bio-Based Data Equivalence and Read-Across**	Reduce duplication and costs in data generation by recognizing comparable safety data across bio-derived analogues.	Amend UK REACH guidance to include bio-based read-across provisions. Harmonise non-animal testing and data acceptance across agencies.	HSE	**High**	**Medium**
4	**Integrate Sustainability Criteria into Regulatory Decisions**	Embed environmental and circularity metrics into safety and impact assessments.	Introduce sustainability indicators (e.g., carbon intensity, recyclability) into regulatory impact assessments. Include sustainability-linked procurement and market incentives for approved materials.	OPSS / Defra /DESNZ	**Medium**	**High**
5	**Strengthen International and Standards Alignment**	Ensure UK leadership and global market access for sustainable materials.	Engage via OECD and WTO to harmonise definitions, testing standards, and data recognition. Update UK FCM and cosmetics regulations to include bio-based positive lists.	DBT / Defra / HSE	**Medium**	**High**

Introduction

The case for bio-based chemicals and materials

The UK's *Modern Industrial Strategy*[1] sets out an ambitious vision: by 2035, the UK will stand among the world's top three hubs for creating, investing in, and scaling fast-growing technology businesses. Central to this ambition is achieving the UK's first trillion-dollar technology company—an aspiration that depends on bold, urgent reform of the regulatory environment to foster innovation and global competitiveness.

At the heart of this vision lies Engineering Biology — the cornerstone of the modern industrial bioeconomy - and one of the *Modern Industrial Strategy's* eight growth-driving sectors (IS-8)[10]. By harnessing renewable resources such as plants, microorganisms, and organic waste, it enables the sustainable design and manufacture of chemicals and materials. This transition away from fossil-based products reduces greenhouse gas emissions, minimises waste, and supports circular economic models where resources are continually reused and recycled within biological systems[11].

In addition, a range of other government policies and industry initiatives—including the *National Materials Innovation Strategy*[12]*, UK Packaging Pact*[13]*, Delivering a Net Zero NHS Strategy*[14], all emphasise bio-based chemicals, materials and products as central to delivering both economic growth and environmental benefits.

The Size of the Prize

Globally valued at over £30 trillion by 2050[15], the modern industrial bioeconomy represents a transformative opportunity for the UK. For engineering biology, the government has already committed £2 billion over the next decade, including £380 million for research, development, and infrastructure to scale bio-based products[16].

The UK's modern industrial bioeconomy today comprises more than 1,200 businesses, around 1,100 of which are SMEs. In 2024, the sector generated over £12.5 billion in revenues, contributed £5.1 billion in GVA, and supported more than 20,000 high-value jobs[17].

Already, bio-based chemicals and materials are transforming manufacturing across sectors: from plastics and packaging to food, textiles, energy, batteries, defence, communications, healthcare and cosmetics. These innovations are vital to our food security, national resilience, and well-being.

With the right policy and regulatory support, bio-based chemicals and materials could generate upwards of £204 billion in annual revenue for the UK by 2050[18]. In addition, evidence suggests that adopting the commercial production of just twelve high-potential bio-based chemicals could deliver 5.2 million tonnes CO_2e in annual GHG savings - greater than the total CO_2e savings achieved through the Road Traffic Fuel Obligation in 2021[19].

[10] Industrial Strategy Sector Definitions List - GOV.UK
[11] What is the bioeconomy? - BBIA
[12] National Materials Innovation Strategy - Henry Royce Institute
[13] UK Packaging Pact | WRAP - The Waste and Resources Action Programme
[14] delivering-a-net-zero-national-health-service.pdf
[15] https://www.naturefinance.net/wp-content/uploads/2024/05/ENG-TheGlobalBioeconomy_FINAL.pdf
[16] assets.publishing.service.gov.uk/media/6892104df15b237bf6610996/industrial_strategy_digital_and_technologies_sector_plan
[17] Perspective Economics, 2025, Unpublished
[18] iuk-business-connect.org.uk/wp-content/uploads/2024/08/IUK-Sustainable-Carbon-Report.pdf
[19] Project contract PS22436 - Economic and climate benefits to the UK of an increased use of bio-based chemicals (RAF097/2223), Authored by NNFCC, FREY and Perspective Economics

Regulations hindering innovation and real-world impact

However, despite strong policy intent, the UK's regulatory framework for the bio-based chemicals and materials sector remains outdated, fragmented, and at odds with innovation[20]. Current systems such as UK REACH, and OPSS cosmetic regulations are historically structured around fossil-based inputs, creating unnecessary delays and ambiguity for novel bio-based chemicals and materials. These inefficiencies discourage investment, hinder SME competitiveness, and risk the UK falling behind global leaders such as the US, EU, and Singapore — countries actively modernising their regulatory systems to promote bio-based innovation[21].

Independent BBIA[22],[23] research and stakeholder consultation confirm that the UK's current policy and legislative frameworks fall far short of enabling bio-based producers to meet national sustainability and economic growth goals. These regulatory bottlenecks are causing measurable losses in GVA, green jobs, and investment — threatening the UK's competitiveness and its Net Zero trajectory.

Government ambitions for regulatory reform

The Government is committed to accelerating regulatory reform to drive innovation, strengthen the UK's global competitiveness, and deliver sustainable growth.

They are taking forward a coordinated set of actions to support the commercialisation and scale-up of bio-based chemical and materials. These actions include establishing a new Infrastructure Fund to address the scale-up challenge, implementing an ambitious R&D programme to stimulate innovation, and tackling regulatory barriers that delay or prevent routes to market for new products.

In addition, building on the success of the engineering biology regulatory sandbox funding awarded to the Food Standards Agency[24] - which aims to test innovative regulatory approaches for products like cultivated meat – Government has committed to expand this approach to support wider regulatory reform across other sectors.

A key element of this regulatory reform is the creation of the new Regulatory Innovation Office, which will provide a more coherent, supportive, and innovation-friendly regulatory environment. The Office will work across government and with regulators to identify opportunities for reform, streamline regulatory processes, and ensure that regulation keeps pace with technological change.

The overarching goal is that the Government has also committed to reducing the administrative cost of regulation for businesses by 25% by the end of this Parliament[25].

This report takes these ambitions forward by identifying specific opportunities to reduce the burden and complexity of complying with existing regulation, and by setting out practical steps to make the regulatory system more agile, transparent, and innovation friendly. In doing so, it seeks to ensure that the UK's regulatory environment actively supports growth, investment, and technological advancement across engineering biology and the modern industrial bioeconomy.

[20] BBREGNET_Addressing-the-UKs-polysemous-bioeconomy-_A-call-for-policy-cohesion.pdf
[21] From Research to Revenue: The Case for Scaling UK Bio-based
[22] www.bbia.org.uk
[23] Resource Hub - BB-REG-NET
[24] Engineering Biology Sandbox Fund - GOV.UK
[25] New approach to ensure regulators and regulation support growth (HTML) - GOV.UK

Current UK Regulatory Landscape

A regulatory landscape based on fossil consumption

To be successful, companies need three practical things from regulators:

1. Predictable timelines and decision rules
2. Proportionate risk-based data requirements
3. Market incentives or procurement channels that reward sustainability.

Through our stakeholder engagement we identified several significant regulatory and systemic barriers currently constraining the growth and competitiveness of the UK's bio-based and circular materials sector.

While the UK has world-leading research and early-stage innovation in bio-based technologies, companies face regulatory systems that are outdated, fragmented, and not designed for the novel aspects of bio-based chemicals, materials and products. Though UK regulations are feedstock-neutral in principle, in practice they remain fossil-biased -reflecting legacy testing standards, performance benchmarks, and cost structures designed around petrochemical products. As a result, commercialisation is slow, investment is deterred, and SMEs are disproportionately affected.

Our recent *Bio-Barometer Survey*[26] assessed the current landscape, opportunities, and challenges in the bio-based chemicals and materials sector gathering insights from over 100 key stakeholders, including manufacturers, policymakers, researchers, and consumers.

Stakeholders cited strategy and policy (including regulations) as the second largest barrier to commercialisation (Figure 1) of bio-based chemicals and materials, with the UK's bio-based policy framework being highlighted as inadequate (rated 2.49/5), with no strong incentives, or positive regulations for market development. For the policy and regulatory landscape, regulations were highlighted as being the most significant barrier, followed by policy, standards, and certifications (Figure 2).

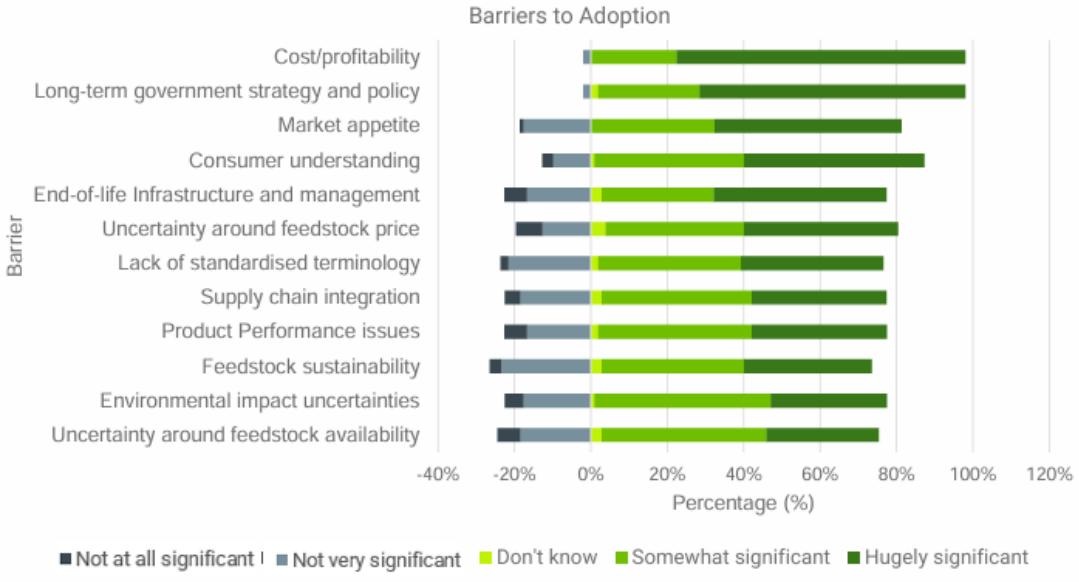


Figure 1. Barriers for commercialisation of Bio-based chemicals and materials

[26] Shaping the future of sustainable materials in the UK

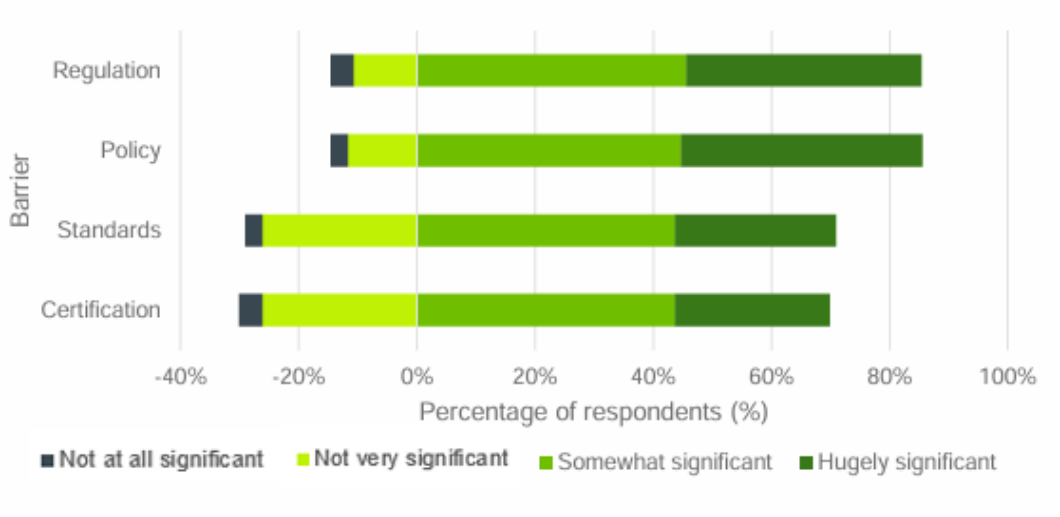


Figure 2. Strategy and Policy Barriers for commercialisation of Bio-based

Key challenges in UK bio-based product regulation include:

- **Complex and Outdated Framework:** The current UK regulatory system covers both individual substances (via REACH) and product end uses, such as cosmetics (via OPSS) or foods (FSA), with differing approval processes and safety assessments. Conflicts can arise - for example, REACH requires animal studies for acute oral toxicity, while the Cosmetics Regulation prohibits them. Stakeholders also note that the current regulatory framework is falling behind advances in biologically engineered ingredients, which often require more advanced or rigorous testing to account for their unique characteristics.
- **Lengthy and Costly Authorisation:** Approval processes are slow, complex, and expensive, with no statutory service level agreements, specifying timelines. SMEs face disproportionate burdens due to limited resources and venture capital cycles. Bio-based innovations often encounter additional delays from novel testing methodologies, which may not be accepted by regulators.
- **UK REACH Procedural Burdens:** New UK REACH registrations require full IUCLID dossiers and Article 26 inquiries. Lack of acceptance of EU REACH registrations forces duplication of work, increases costs and timelines, and discourages early-stage bio-based innovation.
- **Materials Falling Between Regulatory Gaps:** Emerging bio-based materials, such as fibre-based packaging, algae-derived films, and mycelium trays, often lack clear regulatory categorisation. Applicants are passed between agencies (HSE, FSA, OPSS, Defra) with no unified assessment. UK Food Contact Material regulations, based on retained EU law, lack updated positive lists for bio-based additives, forcing full migration testing even for materials approved in the EU.
- **Fragmented and Duplicative Dossier Requirements:** A single bio-based chemical may require parallel submissions under UK REACH, FSA, and OPSS, each with differing data formats, testing, and evidentiary standards. The absence of mandatory data-sharing multiplies duplication, slows market entry, and creates inconsistent outcomes.
- **Non-Differentiated Risk Assessment:** Current regulations rarely distinguish fossil-based from bio-based products, applying identical safety tests despite differing environmental and toxicological profiles. No streamlined routes exist for bio-based alternatives, leaving novel feedstocks subject to high barriers for hazard characterisation.

- **Non-Animal Testing and Data Gaps:** Despite public support for non-animal testing, no harmonised acceptance framework exists. Companies investing in in vitro or computational methods face inconsistent recognition across REACH, FSA, and OPSS. Coordinated acceptance could accelerate innovation and strengthen the UK's science-led regulatory position.
- **Fossil Bias in Assessment Frameworks:** Regulations remain biased toward petrochemical products due to legacy testing standards, performance benchmarks, and cost structures. Life cycle assessment methodologies can make sustainable products appear up to 103% more environmentally damaging, distorting metrics, undermining bioeconomy investment, and hindering UK Net Zero progress.

Innovation stifled, economic impact delayed

These inefficiencies discourage investment, hinder SME competitiveness, and risk the UK falling behind global leaders such as the US, EU, and Singapore — countries actively modernising their regulatory systems to promote bio-based innovation[27].

This creates three critical risks:

1. **Company Exodus:** UK bio-based SMEs are relocating to countries with more supportive regulatory environments, resulting in the loss of jobs, IP, and taxpayer-funded innovation. Our report, *From Research to Revenue*: *The Case for Scaling UK Bio-based Innovation*[28] demonstrates the sector's untapped potential: with the right regulatory framework and infrastructure, scaling UK bio-based SMEs could create up to 4,230 high-value jobs and generate £300–500 million in additional GVA. Without a predictable, efficient, and innovation-friendly pathway to market, UK innovators are increasingly moving to jurisdictions like the US and Singapore.
2. **Investment Drain & Company Failure:** Regulatory uncertainty and long timelines increase investor risk, causing startups to fail or downscale and putting billions in public R&D at risk. Over the past decade, several billion pounds of taxpayer-backed funding have supported bio-based research and early-stage development - much of which is now jeopardised by a lack of regulatory follow-through.
3. **Delayed Economic Gains:** Regulatory delays defer significant economic and environmental benefits, including green jobs, tax revenues, and market leadership. Current bottlenecks are slowing the flow of GVA into the UK economy, delaying sustainable alternatives, and limiting national productivity. For just 3 UK-based SMEs the nation is losing £35.7 million in annual GVA—and over 473 potential jobs[29] remain unrealised, representing a significant and avoidable economic drain. With hundreds of similar bio-based SMEs in the UK, the actual annual loss could easily be estimated to be well into the tens of billions.

[27] From Research to Revenue: The Case for Scaling UK Bio-based
[28] From Research to Revenue: The Case for Scaling UK Bio-based
[29] BBIA, unpublished, 2025

Comparative Analysis for Fossil and Bio-Based Cosmetic Ingredients

The beauty industry has always represented more than surface appeal — it is a global force that sets trends, drives innovation, and powers economic growth. Valued at over $300 billion in 2022, the cosmetics market is projected to surpass $418 billion by 2030[30], solidifying its position as one of the largest and fastest-growing sectors worldwide.

Yet, beneath this glamour lies a long-standing environmental concern. For decades, many cosmetic and skincare products have relied heavily on petrochemical-based ingredients such as mineral oils, parabens, and ethylene derivatives — all derived from fossil fuels. The production and disposal of these substances contribute to nearly 10% of global greenhouse gas emissions, while also exacerbating pollution and depleting natural resources. Once washed down drains or rinsed from packaging, these chemicals persist in the environment, contaminating waterways and soil, damaging marine ecosystems, and releasing volatile organic compounds (VOCs) that degrade air quality.

Today, green biotechnology is reshaping this landscape. Advances in engineering biology now allow companies to produce high-performance cosmetic ingredients in laboratories through fermentation processes using microorganisms such as yeast, algae, or bacteria. These bio-based ingredients can replace traditional petrochemicals while offering greater purity, consistency, and dramatically reduced carbon footprints.

A leading example of this shift is Holiferm[31], a UK-based pioneer in sustainable biosurfactant production. The company employs fermentation technology powered by renewable feedstocks such as plant-derived sugars, eliminating the need for petroleum inputs. This approach cuts emissions and energy use while delivering equal — or even superior — performance compared to conventional chemical surfactants. Holiferm's innovation exemplifies how biotechnology can decouple beauty innovation from fossil dependence, paving the way for a cleaner and more ethical cosmetics industry.

However, the path to commercialisation for bio-based cosmetic ingredients remains complex. The process of securing regulatory approval for a novel bio-based cosmetic ingredient — illustrated in the appendix — becomes increasingly complex when engineering biology is involved. Figure 3 and Table 1 outline the pathway for registering a bio-based surfactant produced using a genetically modified organism (GMO).

Note: Although this example focuses on a GMO-based ingredient, the same regulatory process applies to non-GMO variants, excluding the additional GMO-specific requirements.

[30] The-Value-of-Beauty-Report-2025.pdf
[31] Holiferm - Holiferm

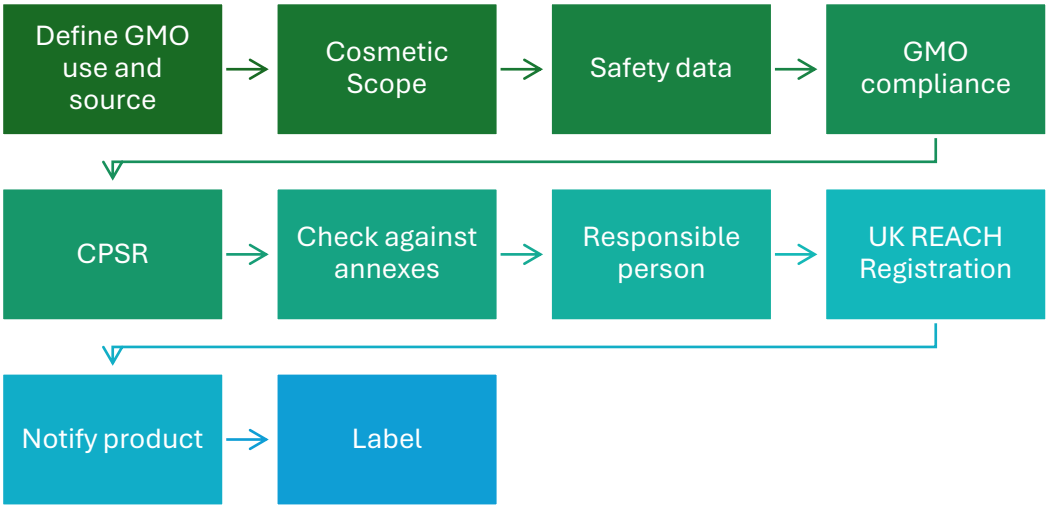


Figure 3. Process for getting a novel bio-based cosmetic ingredient to market, with regulatory approval.

Common Pitfalls for GMO-Derived Cosmetic Ingredients:

- Failing to demonstrate absence of recombinant DNA in the final ingredient.
- Assuming EU REACH or CPNP notifications cover UK — they do not since Brexit.
- Overlooking Contained Use notification for UK-based biotech production.
- Making "eco" or "bio-based" claims without lifecycle or sustainability data.

To highlight the challenges associated with gaining regulatory approval for a novel bio-based chemical in the UK, a comparative analysis was conducted alongside a comparable fossil-derived cosmetic ingredient. This comparison aimed to identify key differences in the regulatory pathways, stages, data requirements, approval timelines, and overall regulatory cost for cosmetic ingredients of differing feedstock origins (Tables 2 & 3, Figure 4, Appendix). An explanation of how best estimates were calculated can be accessed upon request.

By examining both cases, the analysis provides insight into how feedstock origin influences the assessment process under current UK cosmetic and chemical regulations. Table 1 outlines the key steps and considerations involved in ensuring compliance and market readiness for these materials, alongside costs. Figure 3 compares the overall cost of regulatory approval.

Key findings:

- Regulatory approval for a novel fossil-based cosmetic ingredient involves 7 stages, while a bio-based cosmetic ingredient requires 11 stages.
- On average, approval for a novel fossil-based ingredient takes around 50 weeks, compared to 72 weeks for a bio-based ingredient.
- Due to the increased complexity and additional regulatory requirements, the cost of approval for a bio-based cosmetic ingredient is more than double that of a fossil-based one — approximately £815,000 versus £372,000.

Table 1. Step-by-Step: Gaining UK Market Approval for a GMO-Derived Bio-Based Cosmetic Ingredient.

1	**Clarify the Ingredient's Nature and Source. You must establish how genetic modification is used. Most viable cosmetic surfactants fall under Case A — produced *using* GMOs but not themselves GMOs.**

Case	**Example**	**Regulatory Implication**
A. GMO microorganism produces a purified, non-GMO ingredient	e.g. engineered yeast producing biosurfactant (no DNA remains)	Treated as a *chemical/biochemical ingredient* (not a GMO itself)
B. Ingredient contains GMO material (DNA/protein fragments)	e.g. lysed bacterial biomass or enzyme extract	Triggers GMO controls under UK environmental & product safety law
C. Ingredient is a living GMO (e.g. probiotic cosmetic)	e.g. engineered bacteria in formulation	Not permitted under UK cosmetics law

2	**Verify Cosmetic Scope**
Confirm the ingredients 's intended function: Cleansing, emulsifying. If yes → qualifies as a cosmetic ingredient under the UK Cosmetics Regulation (derived from EC 1223/2009). If additional biological activity (e.g. antimicrobial) claimed, may fall under biocide or medicinal regulations instead.	
3	**Regulatory Frameworks Involved. A GMO-derived cosmetic ingredient typically triggers *four* overlapping frameworks:**

Framework	**Applies To**	**Key Authority**	**Core Law**
UK Cosmetics Regulation	Finished cosmetic products	OPSS	Cosmetic Products Enforcement Regulations 2013
UK REACH	Chemical substances (≥1 tonne/year)	HSE	UK REACH Regulation (retained EU 1907/2006)
Contained Use of GMOs	Production process using GMOs	HSE	Genetically Modified Organisms (Contained Use) Regulations 2014
Environmental Release of GMOs	If any GMO traces remain or are released	Defra / EA / SEPA / NRW	Environmental Protection Act 1990, Part VI

4	**Production-Stage GMO Compliance**
If the surfactant is manufactured using a genetically modified microorganism: Notify and comply with Contained Use Regulations (CU1/CU2 notifications to HSE). Classify containment level (CL1–CL4). Cosmetic biosurfactant production is typically CL1 or CL2. Maintain biosafety documentation (risk assessment, waste management, containment plan). You don't need Deliberate Release approval if the GMO does not leave containment. If you *import* the surfactant already purified, your supplier must provide: Declaration that no viable GMO or recombinant DNA is present. Documentation of safe biotechnology practices (ISO 22716 or OECD guidelines).	
5	**Ingredient Safety Data Package**
Compile or obtain a toxicological dossier including full chemical identity (INCI name, CAS, purity, residuals). Source and biotechnological production details (strain, vector, containment). Absence of GMO material (certified by DNA/protein analysis). Toxicology (skin/eye irritation, sensitisation, genotoxicity, systemic toxicity). Biodegradability and ecotoxicity. If similar surfactants have been evaluated by the EU SCCS (Scientific Committee on Consumer Safety) or OECD, reference those.	
6	**Cosmetic Product Safety Report (CPSR)**
When your ingredient is incorporated into a finished cosmetic: The Responsible Person (RP) must ensure a CPSR is conducted by a qualified toxicologist. Include detailed exposure and toxicology data for the new surfactant. Demonstrate that no recombinant DNA/protein remains. Provide margin-of-safety (MoS) calculations for cosmetic use level.	
7	**Check Against Annexes**
Confirm the ingredient: Is not listed in Annex II (prohibited substances). Complies with Annex III restrictions (if applicable). If used as a preservative, colorant, or UV filter → must appear in Annex IV–VI. If it's a novel surfactant, it's likely not listed in any annex, so you rely entirely on the CPSR safety justification.	
8	**REACH Registration (if applicable)**
If you manufacture or import ≥1 tonne/year into Great Britain: Register under UK REACH with the HSE. Supply data on identity, toxicology, environmental safety, and use conditions. If already registered under EU REACH, you may need UK REACH New Registration of an Existing Substance (NRES). or full registration. Cosmetic safety data can often support REACH registration to avoid duplicate testing.	
9	**Responsible Person (RP) and PIF**
For the finished cosmetic product: Appoint a UK Responsible Person. Include your ingredient dossier and CPSR in the Product Information File (PIF). Maintain for 10 years after last market placement. If surfactant is used by *multiple brands*, each RP must include ingredient information in their PIF.	
10	**Notify the Finished Product**
Before placing the finished product on the market: Notify the OPSS via the Submit Cosmetic Product Notification (SCPN) portal. Include: product name, category, RP, ingredient list (INCI), and any nanomaterial info. If the ingredient involves nanotechnology, pre-notify OPSS 6 months prior.	
11	**Labelling and Claims**
Ensure INCI name and claims comply with: INCI naming conventions (consult CosIng for EU reference; still used by UK). Avoid misleading "GMO-free" or "non-GMO" claims unless analytically verified. Claims must comply with UK Regulation (EU) No. 655/2013 on cosmetic claims.	
12	**Post-Market Obligations**
Maintain safety monitoring. Report serious undesirable effects (SUEs) to the OPSS. Update CPSR and PIF for new toxicology or GMO findings.	
13	**Optional (Strongly Recommended)**
Conduct independent third-party verification (e.g. ISO 16128 natural origin index, or RSPO/ISCC certification if plant-based). Keep traceability documentation of your GMO production system for due diligence. Engage early with OPSS and HSE if your ingredient is first-of-its-kind.	

The complexity if exasperated by the numerous government departments and overlapping regulatory requirements of each, as shown in Table 2, where the burden of each regulation (cost and time) for the bio-based cosmetic ingredient producer is RAG rated (RED - High burden, ORANGE, Medium burden, GREEN – Low burden).

Table 2. Government departments involved in regulation of a novel bio-based cosmetic ingredient, and impact. P= Policy Maker, E= Enforcer.

		Department				
Stage	**Action**	**DEFRA**	**OPSS**	**HSE**	**Trading Standards**	**Environment Agency**
1	Land Use and Sustainability	P				E
2	Biodiversity Compliance	P	E			
3	GMO Site Registration	P		E		
4	End-of-Waste Compliance	P	E			E
5	Raw Material Compliance	P	E	E		
6	Chemical Safety Assessment	P		E		
7	Cosmetic Safety Assessment		P / E			
8	Chemical Regulatory Compliance	P		E		
9	Cosmetic Regulatory Compliance		P/E		E	
10	Annex Listing for Cosmetic Regulations		P/E		E	
11	Regulatory Approval		E			

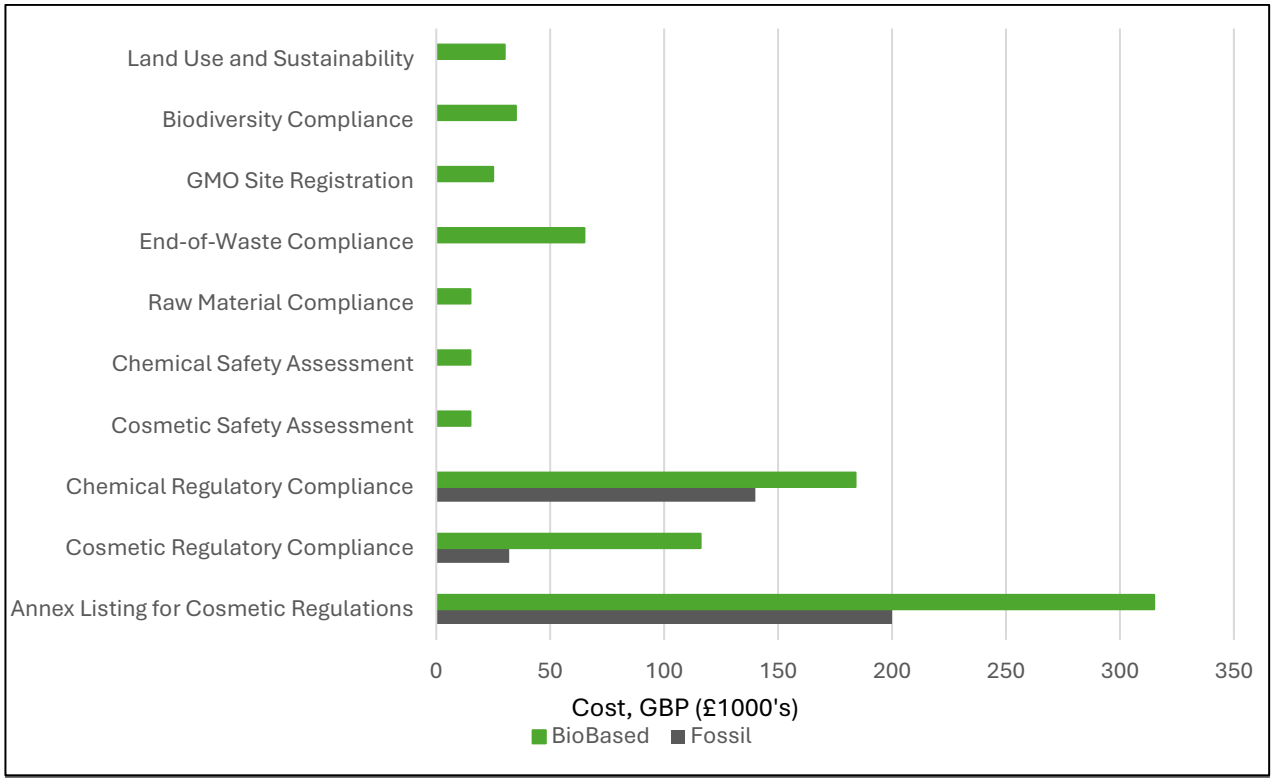


Figure 4. Comparison of the overall cost of regulatory approval for fossil-based and bio-based cosmetics.

Table 3. Key regulatory pathways, stages, data requirements and overall regulatory cost for cosmetic ingredients of differing feedstock origins.

		Cost (GBP, 1,000's)	
Stage	**Action**	**Fossil-based**	**Bio-based**
1	**Land Use and Sustainability:** Ensuring bio-based feedstocks do not compromise food security is increasingly important. Certification processes can be costly and time-consuming, with implications for raw material pricing and feasibility.		30
2	**Biodiversity Compliance:** International agreements such as Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) must be negotiated. This could lead to a % of company profit having to be paid back to the country where feedstock is grown – which can lead to market avoidance of certain feedstocks and regions. This process varies by country and may require legal and consultancy support.		35
3	**GMO Site Registration:** Manufacturing sites must be registered for handling genetically modified organisms. Approval timelines and costs vary depending on the classification of the organism and may require updates to site procedures and infrastructure.		25
4	**End-of-Waste Compliance:** Materials derived from waste must meet stringent criteria under the End of Waste Directive. Approval can take up to two years and incur significant costs, especially for novel materials and processes.		65
5	**Raw Material Compliance:** Bio-based raw materials require extensive documentation, particularly regarding biodiversity and deforestation legislation. Data collection is often hindered by geopolitical factors and lack of clarity in regulatory expectations.	0	15
6	**Chemical Safety Assessment:** Due to the complex nature of bio-based substances (often classified as UVCBs—Unknown or Variable Composition, Complex Reaction Products or Biological Materials), analytical techniques may need to be adapted or developed. Regulatory acceptance of alternative methods is essential, and exact composition may not be fully definable.	0	15
7	**Cosmetic Safety Assessment:** Evaluating bio-based ingredients against cosmetic regulations is more challenging for UVCBs. Without extensive and costly analytical work, it is difficult to identify all chemical constituents. This increases reliance on toxicological testing and impurity profiling, and places greater emphasis on supplier-provided data.	0	15
8	**Chemical Regulatory Compliance:** Toxicological and ecotoxicological data must be generated and submitted. While standard testing protocols exist, they are typically designed for simpler substances. For UVCBs, additional consultation with test laboratories is required to ensure methods are fit for purpose. Limited laboratory expertise and longer biodegradability testing timelines can further delay progress.	140	184
9	**Cosmetic Regulatory Compliance:** Additional toxicological and quality control data (e.g. heavy metals, microbial testing) may be required. These assessments run in parallel with chemical testing but face similar challenges in terms of complexity and duration.	32	116
10	**Annex Listing for Cosmetic Regulations:** A formal dossier must be prepared, often with consultant support. Data from chemical and cosmetic safety studies feed into this process. The complexity of bio-based ingredients may necessitate additional testing and documentation.	200	315
11	**Regulatory Approval:** The final stage involves dossier review, potential consultation, and legislative amendment. For bio-based ingredients, this process may take longer due to increased scrutiny of test methods and data quality, particularly where standard approaches are not applicable to UVCBs.	0	0
	TOTAL COST	**372**	**815**

Summary and Recommendations

The UK is at a pivotal moment in developing its modern industrial bioeconomy. With world-leading research expertise and more than 1,200 UK bio-based businesses, the sector holds the potential to generate over £204 billion annually and create hundreds of thousands of green jobs by 2050. However, this potential is being constrained by outdated, fossil-oriented regulatory systems that remain costly, slow, and fragmented.

BBIA's stakeholder research identifies regulatory complexity as the second-largest barrier to commercialisation. Approval times for bio-based materials are, on average, 45% longer and more than twice as expensive as for fossil-derived equivalents. SMEs in particular face disproportionate burdens — duplicated testing, unclear guidance, and inconsistent requirements across multiple agencies, including HSE, OPSS, FSA, and Defra.

To unlock the full potential of the UK's bio-based chemical and materials sector, an urgent shift toward a coordinated, risk-based, and sustainability - oriented regulatory framework is required. Establishing an integrated regulatory roadmap, promoting data sharing and equivalence, and embedding sustainability criteria into decision-making will position the UK as a global leader in sustainable innovation and manufacturing.

In short, regulatory modernisation is the missing link between the UK's world-class bio-based research and its commercial realisation. Reform will accelerate innovation, attract global investment, and ensure the modern industrial bioeconomy contributes fully to national prosperity and Net Zero ambitions.

Bio-based cosmetic ingredients exemplify both the opportunity and the challenge. They provide a sustainable alternative to fossil-derived materials but face far greater regulatory complexity due to variability in composition, biodiversity considerations, and inconsistent global legislation. While UK regulations are nominally feedstock-neutral, in practice they remain fossil-biased—penalising low-carbon innovation.

This bias extends to environmental assessment methodologies. As highlighted in BBIA's study *Standardised, but Unfair? Challenges in Comparing Bio-Based and Fossil-Based Products Using Life Cycle Assessment*[32]*, where* current frameworks contain methodological flaws that can make sustainable products appear up to 103% more environmentally damaging than fossil equivalents. Such distortions undermine confidence, deter investment, and hinder progress toward the UK's Net Zero goals.

By modernising its chemical and product approval frameworks, the UK can become a global regulatory innovator - one that supports safe, science-based, and sustainable innovation. A coherent, proportionate, and forward-looking regulatory approach will unlock new investment, reduce carbon intensity, and reinforce the UK's leadership in the global transition to a modern industrial bioeconomy.

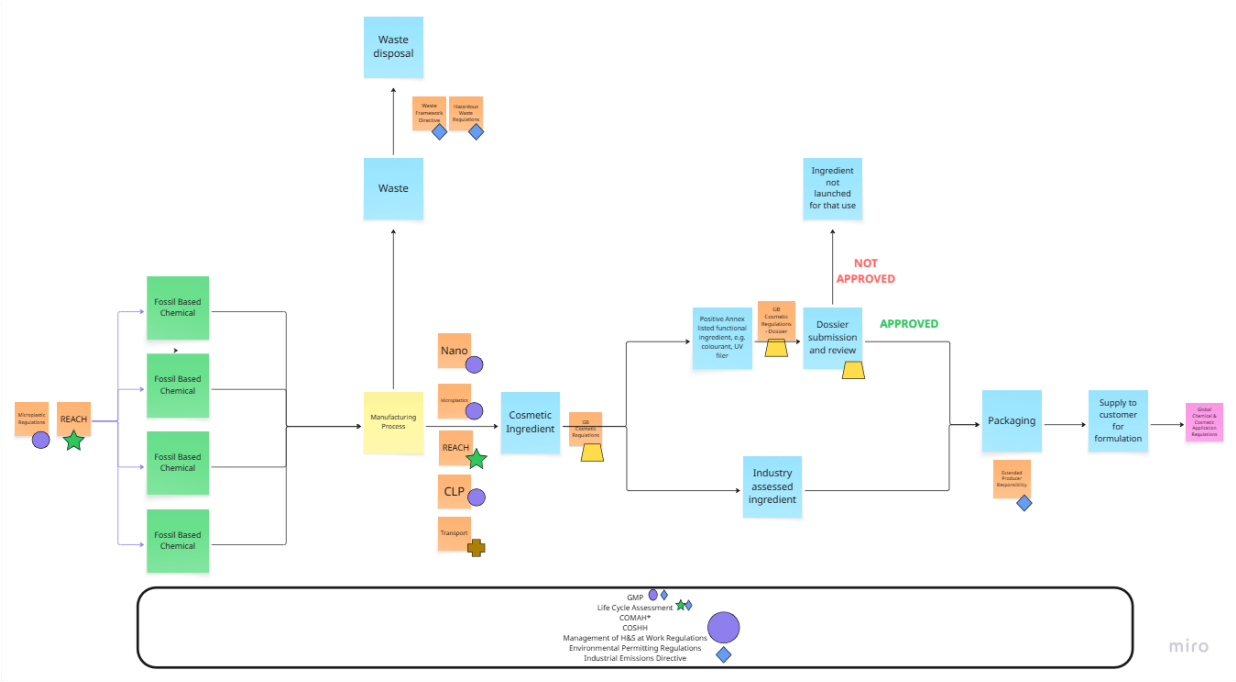
For improving UK regulation of novel bio-based cosmetics ingredients we have 5 key recommends, as shown in Table 4.

[32] Do LCA standards limit comparison?

Table 4. Recommendations for improving novel bio-based chemicals UK regulatory framework

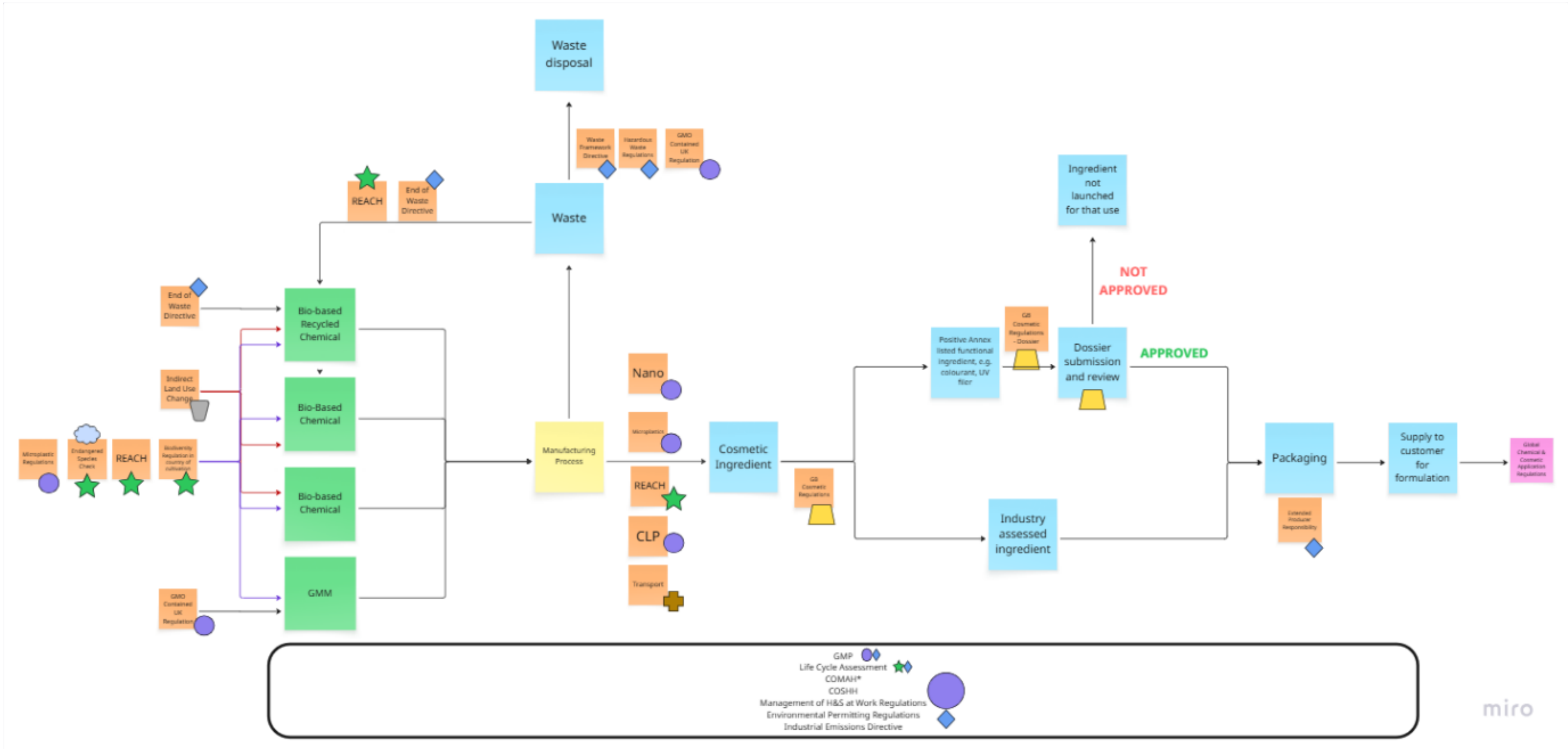
	Recommendation	Purpose	Actions	Lead(s)	Feasibility	Benefit
1	**Utilise Engineering Biology Sandbox Funding to test cross-sector solutions**	Foster coherent, innovation-friendly regulation across chemical and cosmetic, frameworks. Provide a unified, forward-looking framework for sustainable chemical innovation.	Establish a UK Bio-Based Materials Regulatory Roadmap (2026–2030) Define cross-sector alignment goals, pilot fast-track pathways and set clear service-level agreements for approvals. Develop a single-window submission portal for cross-agency coordination.	Defra / DBT / DSIT / (via Coordination Taskforce)	**High**	**High** (Predictable guidance and investment confidence)
2	**Create a Green Innovation Pathway**	Fast-track approvals for low-risk, sustainable, bio-based substances within UK REACH and OPSS frameworks.	Develop proportionate, risk-based routes for low-toxicity materials. Integrate sustainability-linked approval pilots that use lifecycle and circularity data. Consider how this can also transpose to other regulators, e.g. FSA for novel bio-based food contact materials.	Lead: HSE / OPSS /FSA	**Medium**	**High**
3	**Enable Bio-Based Data Equivalence and Read-Across**	Reduce duplication and costs in data generation by recognizing comparable safety data across bio-derived analogues.	Amend UK REACH guidance to include bio-based read-across provisions. Harmonise non-animal testing and data acceptance across agencies.	HSE	**High**	**Medium**
4	**Integrate Sustainability Criteria into Regulatory Decisions**	Embed environmental and circularity metrics into safety and impact assessments.	Introduce sustainability indicators (e.g., carbon intensity, recyclability) into regulatory impact assessments. Include sustainability-linked procurement and market incentives for approved materials.	OPSS / Defra /DESNZ	**Medium**	**High**
5	**Strengthen International and Standards Alignment**	Ensure UK leadership and global market access for sustainable materials.	Engage via OECD and WTO to harmonise definitions, testing standards, and data recognition. Update UK FCM and cosmetics regulations to include bio-based positive lists.	DBT / Defra / HSE	**Medium**	**High**

Appendix



Step	Action	Conditional	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52
1	Ensure RM are compliant for use in manufacture of cosmetic ingredient.																																																							
2	Assessment of chemical regulatory status of manufactured fossil ingredient																																																							
3	Assessment of cosmetic regulatory status of manufactured fossil ingredient																																																							
4	Generation and submission of data to obtain chemical regulatory compliance																																																						
5	Generation and submission of data to obtain cosmetic regulatory compliance																																																						
6	Generation and submission of data for Annex listing on cosmetic regulatory compliance																																																						
7	Approval by regulators for addition to the Annex																																																						

Appendix 1. Regulatory Pathway, and timeline for a novel fossil-based cosmetic ingredient



Step	Action	Time	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72
1	Indirect land use change																																																																									
2	PIC and MAT negotiations for use of BB and GMO with country of origin / cultivation for commercial purposes																																																																									
3	Ensure site compliance / registration to use GMO																																																																									
4	Compliance with End of Waste Directive																																																																									
6	Ensure RM are compliant for use in manufacture of cosmetic ingredient.																																																																									
7	Assessment of chemical regulatory status of manufactured BB ingredient																																																																									
8	Assessment of cosmetic regulatory status of manufactured BB ingredient																																																																									
9	Generation and submission of data to obtain chemical regulatory compliance																																																																									
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11	Generation and submission of data for Annex listing on cosmetic regulatory compliance																																																																									
12	Approval by regulators for addition to the Annex																																																																									

Appendix 2. Regulatory Pathway, and timeline for a novel bio-based cosmetic ingredient