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Executive Summary

SECRETed's biosurfactant and siderophore innovations enter an EU regulatory landscape that is broadly supportive yet still fragmented. Flagship Green-Deal policies—the Chemicals Strategy for Sustainability, Farm-to-Fork and the Circular-Economy Action Plan—prioritise safe-and-sustainable, bio-based chemicals, explicitly encouraging biodegradable surfactants and fast-tracking low-risk microbial inputs. Horizontal rules such as REACH and CLP already apply and will tighten via new hazard classes, reinforcing the need for early compliance data. Sector-specific updates—the Detergents-Regulation recast, the fully applicable Fertilising-Products Regulation (FPR) and forthcoming “microbial detergents” provisions—create new single-market routes for CE-marked biostimulants and greener cleaners.

Opportunity window (2025-28)

- **Public procurement power** – Green Public Procurement, worth $\approx$ €2 trillion a year ($\sim$ 14 % of EU GDP), can create anchor demand for bio-based surfactants in cleaners, coatings and agro-inputs.
- **Economic levers** – Production tax credits, reduced VAT and EIB green-industry guarantees can bridge the cost gap until 10 kt y⁻¹ scale is reached.
- **Climate & circular targets** – Carbon pricing and PFAS / persistent-surfactant bans accelerate substitution; Europe already holds $\approx$ 42 % of the €1.7 bn global biosurfactant market.

Persistent bottlenecks

- Divergent sectoral pathways (biocide vs. cosmetic vs. biostimulant) impose uneven data burdens and create grey zones for dual-use claims (e.g. a siderophore that is both nutrient facilitator and pathogen suppressor).
- No dedicated fast track yet exists for bio-based surfactants under the Biocidal-Products or Plant-Protection frameworks; a full BPR dossier still costs €0.7–1 million and takes 24–30 months.

Strategic recommendations

1. **Secure CE-marking under the FPR** for plant-use products wherever pesticidal claims are not essential.
2. **Exploit WP 8 sustainability proof-points:** -84 % CO₂-eq vs. LAS and a €3 social return for every €1 invested position SECRETed molecules as quintessential “Safe-and-Sustainable-by-Design” candidates, easing REACH dossiers and unlocking EU-Ecolabel extensions.
3. **Shape the standards** – Actively contribute data to CEN EN 17035 ring trials and work with EBIC/IBMA to lobby for a biosurfactant eco-label and a natural-surfactant low-risk annex in the 2026 BPR review.
4. **Stack finance instruments** – Combine CBE-JU or Innovation-Fund grants with national green-tax credits and EIB guarantees to fund the first 10 kt y⁻¹ fermentation plant and reach cost parity with petro-surfactants.

With these advocacy moves, certifications and timed investments, SECRETed can ride the 2025-28 policy wave—turning regulatory change from a hurdle into a launch-pad—and anchor its portfolio as a textbook example of Safe-and-Sustainable-by-Design chemistry.

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1. Introduction

SECRETed (H2020 GA 101000794) employs an **integrated “Design-Build-Test-Learn” pipeline** to mine extremophilic biodiversity, engineer microbial production strains and scale fermentation of tailor-made biosurfactants and amphiphilic siderophores for health, agri-food, cosmetics and environmental applications.

- **Upstream work packages (WPs 1–7)** generate the strains, fermentation processes and downstream purification schemes that define the product specifications to be assessed here.
- **WP8 (Sustainability assessments)** has already produced Deliverables 8.1–8.3, which quantify environmental hotspots (media preparation, fermentation energy, solvent recovery), economic drivers (OPEX dominated by labour and utilities) and social risks in supply chains. These data provide the evidence base for Safe-and-Sustainable-by-Design claims and will be referenced throughout the regulatory analysis.
- Findings from this deliverable will help **WP9 (Exploitation & Dissemination)**, supporting business-plan refinement, investor outreach and standardisation activities, and into **WP3 (Data Platform)** by flagging metadata needed for future compliance documentation.

This assessment follows a **three-layer approach** inspired by EU best practice for “regulatory preparedness” of emerging bio-based technologies:

1. Legislative scan and horizon watching

- Systematic review of horizontal chemicals legislation (REACH, CLP), sectoral frameworks (Detergents, Cosmetics, Fertilising Products, Biocides, PPP, Medicinal Products) and flagship Green-Deal files such as the Chemicals Strategy for Sustainability and Farm-to-Fork Strategy.
- Tracking of forthcoming updates – e.g. Detergents Regulation recast, Safe-and-Sustainable-by-Design (SSbD) criteria, CLP new hazard classes – using official COM proposals and Council/Parliament positions.

2. Compliance gap & barrier analysis

- For each lead application (detergent, cosmetic, biostimulant, therapeutic) the core data requirements, authorisation routes and certification opportunities are extracted from the **Regulatory Assessment** report and benchmarked against SECRETed’s current data package.
- Special attention is given to ambiguities around **amphiphilic molecules** that straddle multiple regulatory categories, as highlighted in the sector-by-sector review of EU and national rules.

3. Integration of sustainability and market-pull evidence

- WP8 LCA/LCC/S-LCA outputs are translated into arguments for SSbD conformity and ecolabel eligibility.
- Downstream market instruments (green public procurement, tax incentives, bio-based quotas) identified in the **Adoption Barriers** analysis are aligned with product launch timelines to maximise early-market traction.

Throughout, the team applied a **stakeholder-validated approach**: draft findings were cross-checked with regulators (ECHA, DG ENV/CLEAN, DG GROW), industry bodies (EBIC, AISE) and standardisation committees (CEN TC 455, CEN/TC 436) during targeted interviews and workshops to ensure practical relevance and up-to-date policy intelligence.

2. Regulatory Landscape Review

2.1 Current Certification & Standards Landscape

Biosurfactant and siderophore developers must navigate a **three-tier certification ecosystem** that moves from horizontal quality systems through sector-specific GMP/GAP schemes to market-facing eco-labels.

Horizontal management standards.

- **ISO 9001** anchors quality management across all manufacturing; buyers in cosmetics and agro-inputs increasingly treat it as a “ticket-to-play”, and notified bodies often verify its presence when auditing CE-marked fertilising products.
- **ISO 14001** is gaining strategic weight because Green-Deal tenders now score suppliers on certified environmental-management systems; holding the certificate lets SECRETed reference SSbD “corporate governance” criteria without additional evidence¹.

Sector-specific GMP / safety schemes.

- **ISO 22716** has become non-negotiable in EU cosmetics since 2013; it covers personnel hygiene, premises, documentation, complaints and recall procedures. Biosurfactant micro-ingredients must come from 22716-certified lines before a Responsible Person can place the finished cosmetic on the market.
- Where amphiphilic molecules are embedded in **drug-device combinations**, the quality system must escalate to **ISO 13485**, aligning batch-release and traceability with EMA Annex I requirements.
- Food-grade siderophores marketed as iron fortifiers will trigger **ISO 22000/FSSC 22000** or HACCP audits of fermentation and downstream-purification steps to demonstrate allergen and pathogen control.

Test-method & data-integrity frameworks.

- **GLP plus relevant OECD Test Guidelines** (e.g., 301 A–F for ready biodegradability) are explicitly required in REACH and BPR dossiers; non-GLP data are routinely rejected by ECHA rapporteurs.
- For human trials, **GCP** applies; animal-rule waivers are increasingly accepted for topical biosurfactants in cosmetics dossiers if validated in-vitro skin-irritation methods (OECD 439) are provided.

Eco- and bio-based labels.

- A reformatted **EU Ecolabel** (under revision) now awards up to 3 points for surfactants with ≥ 80 % renewable-carbon content and ultimate biodegradability — a direct pull for SECRETed’s rhamnolipids.
- **EN 17035 (2022)**, the first dedicated biosurfactant standard, defines terminology, renewable-carbon thresholds, and test protocols for surface activity, toxicity and biodegradation. Early compliance will smooth customs checks across Member States once inspectors receive the CEN guidance².

¹ https://research-and-innovation.ec.europa.eu/news/all-research-and-innovation-news/recommendation-safe-and-sustainable-chemicals-published-2022-12-08_en

² <https://standards.iteh.ai/catalog/standards/sist/2404dbb7-adc5-4768-80fc-eeb85bdaa4e7/sist-en-17035-2022?srsltid=AfmBOooT1usj5K9ajiKlykobhvrZoqu2lkHWnVfkSXjasIMsyX7SQWzO>

- **OMRI** and EU organic-input lists exclude GMO-derived ingredients; if strains used in fermentation are genetically edited, SECRETed must prove absence of recombinant DNA to keep organic-market access.

3.2 Legislative Framework (Upstream)

Green-Deal anchor strategies create the umbrella objectives:

- The **Chemicals Strategy for Sustainability** introduced *Safe-and-Sustainable-by-Design (SSbD)* as the future filter for R&I funding and will embed SSbD scoring into REACH information requirements over the next revision cycle.
- The **Farm-to-Fork Strategy** mandates a 50 % reduction in synthetic-pesticide use and 20 % reduction in fertiliser inputs by 2030, directly increasing demand for siderophore biostimulants and biosurfactant-based biocontrol agents³.
- The **Circular-Economy Action Plan** adds *Digital Product Passports* and resource-efficiency scoring, already visible in the Detergents-Regulation recast which allows mandatory label data to migrate onto QR codes⁴.

Horizontal & sectoral rules set concrete obligations:

- **REACH** registration ($\geq 1 \text{ t y}^{-1}$) remains the default legal gate; the 2023 CLP amendment added hazard classes for endocrine disruption and *PMT/vPvM* persistence profiles, so even “green” surfactants must supply chronic-toxicity and mobility data.
- **Detergents Regulation (648/2004) → COM(2023) 217** will recognise “microbial detergents”, introduce product passports and maintain ultimate-biodegradability testing — a triple advantage for SECRETed biosurfactants that can present OECD 301 data digitally.
- The **Fertilising-Products Regulation** already opened an EU single market for plant biostimulants; siderophore iron-chelates fall under **PFC 6(B)** while live producing microbes fall under **PFC 6(A)**, enabling CE-mark once efficacy and safety are proven).

Near-term regulatory milestones (2024-2027).

- The **SSbD Commission Recommendation** became operational in 2024; Horizon-Europe calls now ask proposers to include SSbD self-assessment sheets.
- Draft **REACH revision** texts indicate mandatory polymer registration and a *review-every-10-years* validity rule; SECRETed’s amphiphilic congeners may therefore require dedicated dossiers.
- Delegated acts under the detergent recast (expected 2026-27) will define lab test methods for microbial detergents and may modernise biodegradability protocols to better accommodate complex biosurfactant mixtures.

3.3 Regulation of Amphiphilic Molecules

Current treatment

Biosurfactants and siderophores lack a standalone legal definition; regulators instead apply *intended-use* logic. A single rhamnolipid can therefore travel three divergent legal corridors: FPR (biostimulant), Detergents (cleaner), or BPR (biocide), each with different data burdens — a major compliance-cost driver for SMEs⁵. The amphiphilic nature is irrelevant per se; hazard assessments focus on toxicity, persistence and endocrine activity, while GMO rules

³ Silva V, Yang X, Fleskens L, Ritsema CJ, Geissen V. Environmental and human health at risk - Scenarios to achieve the Farm to Fork 50% pesticide reduction goals. *Environ Int.* 2022 Jul;165:107296. doi: 10.1016/j.envint.2022.107296

⁴ <https://www.europarl.europa.eu/legislative-train/theme-a-european-green-deal/file-revision-of-the-detergents-regulation>

⁵ <https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/list-of-approved-active-substances>

apply only if producer strains are released or if recombinant DNA remains in the final product.

Persistent gaps & uncertainties

Gap	Practical impact
Dual-use ambiguity – same molecule could be a nutrient chelate <i>or</i> mild antimicrobial	Firms must choose either the lighter FPR path or the heavier PPP/BPR path; national authorities have rejected borderline dossiers when in doubt.
Congener mixtures vs. REACH “one-substance” paradigm	Rhamnolipid mixtures need novel substance-identity arguments; ECHA guidance on UVCB bio-surfactants remains limited, causing dossier delays.
No natural-active fast track in BPR	Biosurfactant disinfectants face the same € >1 m dossier costs as synthetic actives; this discourages innovation despite low hazard profiles.
Scarce guidance on environmental fate of siderophores	Risk assessors lack standard tests for heavy-metal mobilisation/chelation; dossiers risk “data waiving not accepted” remarks.

Regulatory trajectory

All major revisions underway (Detergents recast, PPP micro-organism acceleration, SSbD roll-out) explicitly reference bio-based or biotech alternatives, signalling a **progressive pivot toward clearer—and generally more favourable—treatment** of amphiphilic biomolecules.

3. Market Access & Down-stream Instruments

The EU no longer relies on a single lever to scale sustainable chemistry; instead, it combines **financial carrots, legal sticks and long-term strategic signals** that together shrink the risk premium for first-of-a-kind bio-based surfactant plants while simultaneously pushing incumbents out of the market. Below, each instrument is unpacked beyond the headline tables to show where SECRETed can intervene and what evidence (often generated in WP 8) will be persuasive.

3.1 Economic instruments

The cost gap between petro-surfactants and second-generation biosurfactants narrows rapidly when public finance absorbs part of the capital- or carbon-transition risk.

Tax incentives.

Several Member States already offer *enhanced R&D allowances* for low-carbon processes, and a 2022 Commission study proposed *reduced VAT* rates for certified environmental products to accelerate market penetration. SECRETed can prepare a policy brief quantifying the **84 % CO₂-eq reduction** shown in WP 8 and illustrate the fiscal pay-back of a 5 % VAT rebate on every tonne of rhamnolipid sold.

EU-level grant and equity funds.

Horizon Europe and the **Circular Bio-based Europe JU (CBE-JU)** regularly ring-fence calls for demo plants; CBE-JU's current **SURFs UP** project funds nine biosurfactant scale-ups, setting a template for SECRETed's WP 6 assets⁶. The **EU Innovation Fund** then provides up to 60 % CAPEX/OPEX support for first-of-a-kind, low-carbon chemical plants—including fermentation facilities—using revenues from the EU-ETS.

Blended finance and loan guarantees.

When projects graduate from grant funding, **EIB green-industry guarantees** or InnovFin Demo Project loans cut interest rates by 200–300 bp, a critical margin when projecting pay-back for 10 kt y⁻¹ fermentation lines.

Public–private partnerships (PPPs).

Legacy BBI-JU consortia have demonstrated that a 50 % public co-funding share derisks pilot-to-first-plant transitions; SECRETed can replicate that model by assembling a PPP on *amphiphilic siderophores* (fertiliser & medical niche) under the next CBE-JU work programme.

3.2 Regulatory measures that create demand

Bio-based content quotas.

Although no EU-wide quota exists yet, a CE-Delft impact study for DG ENV shows that mandating **30–55 % bio- or recycled-carbon** in plastics could be feasible by 2030; detergents and agrochemicals are being discussed as the next candidate sectors. France and the Netherlands have started exploring national quota pilots—valuable precedents to cite in advocacy briefs.

Green Public Procurement (GPP).

The Commission's common GPP criteria for cleaning products already include extra points for surfactants passing **OECD 301** and showing low aquatic toxicity⁷. Vetted WP 8 data will let SECRETed draft “ready-to-insert” criteria for ministries and city councils—thereby securing an anchor customer base.

Targeted bans & restrictions.

History shows how bans stimulate substitution: when phosphates were banned from consumer

⁶ <https://www.cbe.europa.eu/projects/surfs-up>

⁷ https://green-forum.ec.europa.eu/green-public-procurement/gpp-criteria-and-requirements_en

detergents in 2013, formulators shifted toward enzymatic and biosurfactant boosters within 18 months. Two upcoming regulatory waves will repeat the pattern:

- the broad **PFAS restriction** proposal, which also covers certain fluorinated surfactants, is under ECHA scrutiny⁸;
- a Green-Deal initiative to label or restrict **persistent, mobile and toxic (PMT)** surfactants under REACH and CLP.

SECRETed can position rhamnolipids as *drop-in*, PFAS-free replacements and file a **substitution dossier** during ECHA public consultations.

3.3 Strategic, long-range drivers

Carbon pricing & CBAM. By 2027 the reformed EU-ETS will expand coverage to 78 % of EEA emissions, and BloombergNEF projects the carbon price to exceed € 140 t⁻¹ CO₂ by 2030⁹. A **carbon border adjustment mechanism (CBAM)** will apply a similar cost to imported chemicals, further eroding the cost advantage of petro-surfactants¹⁰. WP 8's carbon-footprint data therefore turn into *monetisable Scope-3 credits* for downstream FMCG brands.

Circular-Economy Action Plan & Digital Product Passports. From 2026 detergents will need machine-readable passports listing chemical hazards and sustainability scores; products meeting future **SSbD metrics** are expected to gain “green-lane” status in customs and procurement systems. SECRETed should pilot passport prototypes using CEN EN 17035 test data and WP 8 LCA results.

Mission-oriented funding. Horizon-Europe **Mission “A Soil Deal for Europe”** and **Mission “Restore our Ocean”** both finance deployment of biodegradable, bio-based remediation tools. Siderophore formulations that mobilise iron or bind heavy metals could secure pilot funding and deliver high-visibility demonstration sites.

3.4 Key take-aways for SECRETed

1. **Layer incentives:** Combine CBE-JU grants, national tax credits and EIB guarantees to bring internal rates of return for the first commercial plant above 12 %.
2. **Write the rules:** Deliver pre-drafted GPP language and substitution dossiers so policymakers can adopt biosurfactant-friendly criteria with minimal red-tape.
3. **Surf the bans:** Track PFAS and PMT restriction timelines; synchronise rhamnolipid dossier submission so the product is market-ready exactly when incumbents exit.
4. **Sell carbon relief:** Package WP 8 CO₂-savings into Scope-3 certificates and offer them to detergent and agro-input multinationals that need rapid decarbonisation.

These combined levers—**economic de-risking, regulatory push and strategic pull**—create a **reinforcing feedback loop**: every new policy signal raises the cost of sticking with petro-surfactants while lowering the barrier to adopting SECRETed's safe-and-sustainable alternatives.

⁸ <https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas>

⁹ <https://about.bnef.com/insights/finance/europes-new-emissions-trading-system-expected-to-have-worlds-highest-carbon-price-in-2030-at-e149-bloombergnef-forecast-reveals/>

¹⁰ <https://www.reuters.com/sustainability/climate-energy/eu-countries-agree-exempt-most-firms-carbon-border-tariff-2025-05-27/>

The five SECRETed product lines each face a different “regulatory personality.” Below you’ll find an expanded explanation—moving beyond the matrix—of how every line matches (or collides with) EU policy, what the competitive SWOT looks like, and which concrete risk-management moves have the best payoff.

4. Viability Check of SECRETed Products

4.1 From science to licence: how each product tracks through EU law

Siderophore iron-chelates ⇒ CE-marked biostimulants

The Fertilising-Products Regulation (FPR) opened a single market for plant biostimulants in July 2022. Iron-chelating siderophores fit neatly in **PFC 6(B)** (non-microbial chelated micronutrients) while a living production organism can be placed in **PFC 6(A)**. Once the CE

mark is affixed, national “parallel registrations” disappear, cutting time-to-market by roughly 18 months and €80 k per Member State¹¹. The only caveat: if pesticidal claims creep into the label, the product is pushed into the far heavier Plant-Protection route under Reg. 1107/2009.

Rhamnolipid detergents & cosmetics

Under current Detergents Reg. 648/2004, the sole gate is the **ultimate-biodegradability test (OECD 301)**. The 2023 recast proposal (COM(2023) 217) keeps that test but adds a legal definition of “microbial detergents” and digital product passports—explicitly recognising fermentation-derived surfactants and giving formulators a marketing story around traceability^{12,13}. For cosmetic use, rhamnolipids migrate into Reg. 1223/2009; ISO 22716 GMP documentation plus a Cosmetic Product Safety Report are mandatory, but REACH duties drop away so long as annual tonnage stays below 1 t.

Biosurfactant / siderophore biocides

Any antimicrobial claim triggers the **Biocidal Products Regulation (BPR)**. Article 25 does provide a *simplified authorisation track* for “natural low-risk actives”, cutting the data package roughly in half—but only three surfactant-type substances sit on the current list and none are microbial-derived. dossier fees still hover at €70–120 k per product family even in small Member States, so early dialogue with ECHA to add rhamnolipids to the low-risk list is critical.

Siderophore–drug conjugates / API excipients

EMA’s centralised procedure (Dir. 2001/83/EC + Reg. 726/2004) remains the gold standard. In 2023 the Commission inserted **transferable exclusivity vouchers** into the draft pharmaceutical reform to reward innovative antibiotics—worth up to one extra year of blockbuster exclusivity, potentially adding €0.5–1 bn NPV for a first-in-class siderophore antibiotic¹⁴. Environmental-risk assessments (ERA) are becoming stricter, so WP 8 data on fast biodegradation are a commercial asset here.

Food & nutraceutical uses

Purified siderophore or glycolipid ingredients not “traditionally consumed” require a **Novel-Food authorisation** under Reg. 2015/2283. EFSA’s 2024 guidance spells out data on identity, ADME, and nutritional impact that must be generated; once authorised, the substance enjoys a five-year data-protection window and is exempt from REACH¹⁵.

4.2 SWOTanalysis

Strengths. SECRETed molecules check the boxes regulators now reward: renewable carbon, ready biodegradability, and—crucially under the 2023 CLP amendment—**low persistence & mobility** so they avoid the new PMT / vPvM hazard classes¹⁶. That profile dovetails with Green-Deal bans on microplastics (Reg. 2023/2055) and PFAS, giving rhamnolipids an incumbent-replacement story^{17,18}.

Weaknesses. Unit cost remains ≥ 20 % above LAS or SLES at sub-10 kt scale, and the regulatory landscape fragments once dual claims appear (biostimulant vs. pesticide; disinfectant vs. detergent). Guidance for complex **UVCB** (unknown/variable composition) substances like rhamnolipid congeners is still thin, slowing dossier assembly.

¹¹ <https://eur-lex.europa.eu/eli/reg/2019/1009/oj>

¹² https://single-market-economy.ec.europa.eu/publications/com2023217-proposal-regulation-detergents-and-surfactants_en

¹³ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52023PC0217>

¹⁴ Berner-Rodoreda A, Cobelens F, Vandamme AM, Froeschl G, Skordis J, Renganathan E, t’Hoen E, Raviglione M, Jahn A, Bärnighausen T. Transferable data exclusivity vouchers are not the solution to the antimicrobial drug development crisis: a commentary on the proposed EU pharmaceutical regulation. *BMJ Glob Health*. 2024 Feb 28;9(2):e014605. doi: 10.1136/bmjgh-2023-014605. PMID: 38423550; PMCID: PMC10910522.

¹⁵ <https://www.efsa.europa.eu/en/efsajournal/pub/8961>

¹⁶ <https://echa.europa.eu/new-hazard-classes-2023>

¹⁷ <https://eur-lex.europa.eu/eli/reg/2023/2055/oj>

¹⁸ <https://echa.europa.eu/hot-topics/microplastics>

Opportunities. The **CE-marked biostimulant** corridor is the first truly borderless EU route for agro inputs. In detergents, the recast will push QR-coded labels and explicit sustainability scoring, allowing SECRETed to showcase LCA wins. Horizon-Europe and CBE-JU calls now require SSbD self-assessment sheets—meaning applicants with compliant surfactants are automatically more competitive.

Threats. If the BPR low-risk list is not expanded, dossier fees could stall antimicrobial launches; similarly, if “microbial detergent” testing protocols become burdensome in the delegated acts (2026–27) time-to-market could slide by two years. Persistent price-pressure from fossil-based surfactants will persist until carbon pricing or quotas kick in.

4.3 Risk landscape and mitigation actions

High-stakes risk	What IDE R&D should do
€ 0.5 m+ dossier budgets & 30-month clocks (REACH/BPR/PPP)	Bundle toxicology studies inside a Safe-and-Sustainable-by-Design (SSbD) plan so non-critical vertebrate tests can be waived; join an industry consortium to pool “read-across” data and cut cost by up to 40 %.
Dual-use grey zone (biostimulant ↔ pesticide)	Keep first commercial labels strictly on nutrient-uptake claims; in parallel, file an IUCLID “active substance notification” to preserve future PPP options once data are mature.
Price gap vs. petro-surfactants	Push process-yield improvements from WP 6 to $\geq 110 \text{ g L}^{-1}$ titre; layer CBE-JU CAPEX grants, national green-tax credits and EIB guarantees to hit $\leq \text{€}3 \text{ kg}^{-1}$ FOB plant gate.
Method standardisation lag	Contribute ring-trial data to CEN EN 17035 revisions; nominate a SECRETed scientist to TC 455 WG 4 so in-house test methods become part of the reference standard ¹⁹ .
Market trust / greenwashing scrutiny	Obtain EU Ecolabel for detergent-grade rhamnolipids and publish the WP 8 carbon-footprint certificate alongside a third-party verified Product Environmental Footprint (PEF) profile.

Bottom line: each SECRETed product already has at least one **workable, often favourable EU pathway**. The key to viability is not inventing new rules but **navigating the forks**—choosing the lightest regulatory corridor that still meets market claims, then using WP 8 sustainability data plus EU financial levers to neutralise remaining cost and timing barriers.

SECRETed can squeeze far more value out of WP 8 results than a few bullet-points. Below is richer context for how each deliverable plugs directly into dossiers, business decks and lobbying, plus the concrete data-hooks that will persuade regulators and buyers. A single optional infographic—a “data-journey map” linking WP 8 outputs to their end-use in WP 9—would make the flow instantly clear.

¹⁹https://standards.iteh.ai/catalog/standards/sist/2404dbb7-adc5-4768-80fc-eeb85bdaa4e7/sist-en-17035-2022?srsltid=AfmBOoqAE8c0J9uzXjxdht_2d-VBdsSpAYITvVKn776UH7u-sot7tYsa

5. Cross-WP integration: turning numbers into licences, cash and trust

5.1 Integration with Tasks 8.1-8.3

D8 .1 — Baseline LCA/LCC

The cradle-to-gate inventory shows an **84 % lower GHG footprint** for rhamnolipids than for linear-alkylbenzene sulfonate (LAS) cleansers, with media cultivation and steam use dominating impacts^{20, 21}.

Regulatory win: these numbers populate the “*Climate-change*” cell of the Commission’s **Safe-and-Sustainable-by-Design (SSbD)** self-assessment template, which will soon accompany every REACH & Detergent dossier.

D8 .2 — Screening + first recommendations

A mass–energy balance pinpoints labour (31 % OPEX), purification solvents (22 %) and media (19 %) as cost hot-spots, with solvent recovery also topping the eco-hot-spot chart. *Business win:* those slices slot neatly into CBE-JU or Innovation-Fund application forms, which ask for the three largest OPEX items and the top environmental hot-spot.

D8 .3 — Full LCSA + Social-ROI

Social-LCA attributes **95 % of social risk to feedstock agriculture**, while the S-ROI model shows **€ 3 of societal benefit per € 1 invested** in a 10 kt y⁻¹ plant.

Policy win: these metrics map directly onto **Green Public Procurement (GPP)** award criteria for cleaning products, which reward low toxicity, high biodegradability and positive social impacts²².

5.2 Five product attributes that sell themselves

1. **Ready biodegradability** proven by OECD 301B—≥ 60 % CO₂ in 28 days—meets Detergent baseline and anticipates microplastics restrictions.²³
2. **Low irritation & toxicity:** in-vitro OECD 439 data funnel straight into Cosmetic Product Information Files and REACH annex VII.
3. **SSbD alignment:** iterative LCA improvements demonstrate *resource-efficiency* and *toxicity reduction*, matching the Commission’s 2024 SSbD recommendation²⁴.
4. **Proven efficacy:** field trials show siderophore iron-chelates boost Fe uptake by 18 % over EDTA, and lab detergency tests hit LAS cleaning at 30 °C—critical for EU Ecolabel points on performance²⁵.
5. **Policy contribution:** substituting PFAS or PMT surfactants in cleaners and coatings advances Zero-Pollution and Farm-to-Fork goals.

²⁰ <https://doi.org/10.1016/j.biteb.2024.101767>

²¹ Briem, A.K., Bippus, L., Oraby, A., Noll, P., Zibek, S., Albrecht, S. (2022). Environmental Impacts of Biosurfactants from a Life Cycle Perspective: A Systematic Literature Review. In: Hausmann, R., Henkel, M. (eds) Biosurfactants for the Biobased Economy. Advances in Biochemical Engineering/Biotechnology, vol 181. Springer, Cham. https://doi.org/10.1007/10_2021_194

²² https://green-forum.ec.europa.eu/green-public-procurement/gpp-criteria-and-requirements_en

²³ https://www.oecd.org/en/publications/test-no-301-ready-biodegradability_9789264070349-en.html

²⁴ https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/chemicals-and-advanced-materials_en

²⁵ Lurthy T, Cantat C, Jeudy C, Declerck P, Gallardo K, Barraud C, Leroy F, Ourry A, Lemanceau P, Salon C, Mazurier S. Impact of Bacterial Siderophores on Iron Status and Ionome in Pea. Front Plant Sci. 2020 Jun 12;11:730. doi: 10.3389/fpls.2020.00730. PMID: 32595663; PMCID: PMC7304161.

5.3 Clustering & standardisation moves

- **CEN TC 455 / EN 17035** – SECRETed provides ring-trial data so rhamnolipids appear in the first reference table of the 2025 edition.
- **EBIC & IBMA** – joint lobbying for an *expanded FPR component list* and for **BPR low-risk-substance fast track** for natural surfactants.
- **A.I.M.S. bioeconomy cluster** – create a REACH read-across platform to share UVCB ecotox data and shave 40 % off individual dossiers.

5.4 Action checklist (updated)

1. Embed CO₂-saving and S-ROI infographics **in every** pitch deck and dossier.
2. Draft SSbD self-assessment sheets **now**, using WP 8 numbers, so REACH revision surprises none.
3. Schedule a **data FAIR-ification sprint** with WP 3 to make LCA/LCC datasets repository-ready.
4. Feed media-preparation energy KPI back to WP 6 engineers to hit 35 % energy-cut target in the next pilot run.

By weaving WP 8 evidence into the language that **regulators, financiers and buyers already speak**—SSbD scores, GPP points, EIB carbon metrics—SECRETed turns sustainability from a feel-good story into a concrete licence-to-operate and a pricing premium.

6. – Recommendations & Strategic Road-map

A decisive regulatory-finance “window” is opening between 2025 and 2028 when the detergent recast, SSbD framework, PFAS restriction and a first FPR amendment will all land. The roadmap below translates that calendar into concrete lobbying, certification and investment moves, explaining **why each step pays off** and which piece of evidence (mostly from WP 8) should accompany the action.

6.1 Policy-advocacy priorities – what to say, when and to whom

Priority	Expanded action set	Why it matters
Secure a natural-surfactant “low-risk” fast-track in BPR	① Co-author a joint EuropaBio/EBIC note for DG SANTE’s public consultation on the 2026 BPR review . ② Submit WP 8 acute-tox & biodegradability data to back inclusion of rhamnolipids in Annex I (low-risk list).	Only eight substances sit on Annex I today and none are microbial surfactants; adding rhamnolipids would slice dossier costs by > 50 % .
Keep dual-use siderophores inside the FPR	① In EBIC papers ask the Commission to confirm that iron-chelating siderophores without pesticidal claims remain in PFC 6(B) after the 2027 FPR amendment.	Avoiding Reg. 1107/2009 saves 3-4 years and € 3 m data costs.
Hard-wire SSbD into future rules	Present the –84 % GHG and €3 S-ROI case studies from WP 8 at the 5th SSbD stakeholder workshop (Dec 2024) and at CEN/ISO metric drafting sessions.	Early adopters of SSbD will qualify for lighter information sets and better public-procurement scores.
Align test methods & animal-free toxicology	Offer OECD 301 and in-vitro irritation data to CEN TC 455 ring trials that will finalise EN 17035 in 2025.	Ensures SECRETed’s protocols become the reference, boosting dossier acceptability.
Strengthen market-pull levers	Via AISE and national GPP fora lobby for detergent criteria that award ≥ 80 % renewable-carbon surfactant content.	GPP already guides purchases worth ~14 % of EU GDP; criteria revisions happen 2025-26.

6.2 Certification & labelling – narrated rather than tabulated

For plant uses, a **CE-mark** under the FPR is the *passport* to 27 Member States. SECRETed should file a technical dossier as soon as the first pilot batch meets PFC 6(B) spec; an **ISO 9001** certificate for the fermentation plant is normally enough for notified-body audits.

For detergent-grade rhamnolipids, regulatory “musts” are the REACH dossier (> 1 t y⁻¹) and a CLP SDS. To win shelf space, add an **EU Ecolabel**: the criteria under review give bonus points for ultimate biodegradability and renewable-carbon content²⁶. Nordic Swan criteria mirror these and open Scandinavian public-procurement channels.

Cosmetic applications require ISO 22716 GMP plus a Cosmetic Product Safety Report built largely from WP 8 irritation and sensitisation data. A **COSMOS/ECOCERT** mark sends a

²⁶

<https://environment.ec.europa.eu/system/files/2023-07/EU%20Ecolabel%20Work%20plan%202020-2024%20updated%20April%202023%20%281%29.pdf>

clear “non-GMO/natural” signal; ISO 16128 lets you quantify the natural-origin percentage on pack.

Pharma leads follow EMA’s centralised procedure, but the planned antibiotic pull-incentive— a **transferable exclusivity voucher**—adds sizeable upside for siderophore–antibiotic conjugates .

Cross-cutting: once the Commission publishes its SSbD template (expected 2026), file one sheet per product; future ecolabels and GPP tenders will read that score first.

6.3 Regulatory-engagement game-plan

1. **Early-door chats:** ECHA pre-registration meetings (Q4 2025) secure agreement on UVCB substance IDs for rhamnolipids; EFSA scientific advice (2026) clarifies Novel-Food toxicology depth.
2. **Industry task-force:** an EBIC “amphiphilic biomolecule” group can crowd-fund ecotox tests for siderophore iron-chelates and defend their status as *nutrient-uptake boosters*, not pesticides.
3. **Standards shaping:** seeding SECRETed process experts into **CEN TC 455 WG 4** (biosurfactants) ensures lab methods reflect fermentation realities. ISO TC 2389 (just launched) will set global terminology—join now.
4. **Rolling horizon scan:** one junior regulatory analyst spending 0.1 FTE will flag delegated acts on PFAS restriction , CBAM price escalators, or Urban-Wastewater fees, feeding “go/no-go” checkpoints each quarter.

6.4 Policy-window timeline

- **H2 2025 – Detergent recast adoption.** SECRETed should final-proof digital-passport data (ingredient hazards, SSbD score, biodegradability test).
- **2025-26 – First SSbD guidance + EN 17035 publication.** File SSbD sheets and volunteer pilot data for the ring trial.
- **2026 – Pharma law reform.** Engage EMA’s Priority Medicines office to pre-validate siderophore conjugate as an AMR candidate.
- **2026-27 – New pesticide-reduction proposal.** Argue that rhamnolipids fall under “low-risk substances”.
- **2027 – First FPR amendment.** Table evidence to add *siderophore-producing microbes* as a Component Material Category.
- **2028 – Urban-Wastewater polluter-pays fees.** Target personal-care brands fearing fee hikes with PFAS-free, biodegradable surfactants.

6.5 Strategic checklist

1. **Stack incentives.** Combining CBE-JU grants with national tax credits can close the 20 % price-gap to petro-LAS by Year 3 of plant operation.
2. **Data once, use many.** A GLP 90-day oral study can satisfy REACH Annex IX, BPR Annex II and Novel-Food toxicology—saving € 350 k.
3. **Brand with proof.** The –84 % CO₂ badge from WP 8 and an SSbD “green lane” logo differentiate against green-washing competitors now facing Commission “green-claims” enforcement.

4. **Align cap-ex with certification.** Delay full-scale cap-ex until CE-mark (biostimulants) or EU-Ecolabel (detergents) are in hand; this de-risks offtake agreements with agro-inputs and FMCG customers.
5. **Tight advocacy loop.** A quarterly two-page brief lets the exploitation board pivot product sequencing as soon as Brussels moves.

SECRETed's product portfolio is converging with an EU policy cycle that actively removes persistent petro-surfactants while rewarding **safe-and-sustainable bio-based molecules**. Green-Deal flagships—from the Chemicals Strategy for Sustainability (CSS) to the Detergent-Regulation recast—constantly reference biodegradability, renewable carbon and low toxicity as future market tickets. WP 8 data show that rhamnolipids already deliver an 84 % CO₂-eq cut and pass OECD 301 biodegradability—evidence that converts policy rhetoric into a concrete licence-to-operate.

7. Conclusion

EU law now provides at least one **clear, proportionate gateway** for each lead application:

- **Plant biostimulants** – the Fertilising-Products Regulation (EU 2019/1009) offers an EU-wide CE-mark with no additional national permits once conformity is demonstrated²⁷.
- **Detergent ingredients** – ultimate-biodegradability under 648/2004 remains the only hard test, and the 2023 recast explicitly embraces “microbial detergents” and digital product passports.
- **Medical uses** – draft pharmaceutical reforms add a **transferable exclusivity voucher** for novel antibiotics, materially improving the business case for siderophore–drug conjugates.

Demand signals reinforce those gateways:

Green Public Procurement criteria for cleaning products already privilege surfactants meeting OECD 301; PFAS and persistent-surfactant restrictions are advancing through ECHA committees; and carbon-price trajectories ($> \text{€}140 \text{ t}^{-1} \text{ CO}_2$ by 2030) narrow the cost gap to fossil LAS.

Residual risks are (i) dossier cost and complexity when products fall into BPR or PPP channels; (ii) early-stage price premium versus entrenched synthetics. The roadmap mitigates both: SSbD-driven data packages and read-across consortia trim toxicology spend, while layered funding (Innovation Fund, CBE-JU, EIB guarantees) bridge CAPEX/OPEX hurdles.

Alignment with exploitation & sustainability goals

- **Exploitation.** Timelines in Section 7 prioritise **CE-marked biostimulants** and **EU-Ecolabel detergents** as first movers, synchronised with the detergent recast adoption in 2025 and the first FPR amendment in 2027. These dates anchor WP 9 business planning and investor road-shows.
- **Sustainability.** WP 8 proves up to **-84 % GHG** and **€3 social return per €1 invested**; these numbers feed directly into SSbD self-assessments, EU-Ecolabel criteria, and GPP tender documents, transforming ESG compliance into a marketing premium. The same life-cycle evidence helps SECRETed defend access to Innovation-Fund or ETS-backed “green” finance streams.

Closing line

Regulatory change is often cast as a hurdle; for SECRETed it is a **launch-pad**. By executing the advocacy and certification agenda—and by showcasing WP 8 proof-points in every dossier, pitch and procurement bid—the consortium can convert scientific leadership into durable commercial impact while directly advancing the EU’s 2030 pesticide-reduction and 2050 climate-neutrality targets.

²⁷ <https://eur-lex.europa.eu/legal-content/EN/LSU/?uri=celex%3A32019R1009>

8. Additional references

- **REACH** – Regulation (EC) 1907/2006.
- **CLP** – Regulation (EC) 1272/2008 (incl. Delegated Regulation (2023) 707 new hazard classes).
- **Fertilising-Products Regulation** – Regulation (EU) 2019/1009 (OJ L 170, 2019).
- **Detergents Regulation** – Regulation (EC) 648/2004 & recast proposal COM(2023) 217.
- **Biocidal-Products Regulation** – Regulation (EU) 528/2012.
- **Plant-Protection Products Regulation** – Regulation (EC) 1107/2009.
- **Cosmetics Regulation** – Regulation (EC) 1223/2009.
- **Medicinal-Products code** – Directive 2001/83/EC & Regulation (EC) 726/2004 + Pharma-reform COM(2023) 192.
- **Novel-Food Regulation** – Regulation (EU) 2015/2283.
- **Nutrition & Health-Claims Regulation** – Regulation (EC) 1924/2006.
- **Food-Additives Regulation** – Regulation (EC) 1333/2008.
- **Contained-use GMO Directive** – Directive 2009/41/EC.

9.3 Green-Deal & strategic files

- **Chemicals Strategy for Sustainability** – COM(2020) 667.
- **Safe-and-Sustainable-by-Design Recommendation** – C(2022) 9392 + Staff Working Document SWD(2022) 477.
- **Farm-to-Fork Strategy** – COM(2020) 381.
- **Circular-Economy Action Plan** – COM(2020) 98.
- **Impact assessment – Detergent Regulation recast** – SWD(2023) 114/115.
- **PFAS universal restriction proposal** – ECHA Annex XV (2023).
- **Microplastics restriction** – Commission Regulation (EU) 2023/2055.

9.4 Standards, labels & technical criteria

Reference	Latest edition
ISO 9001:2015	QMS – all sectors
ISO 14001:2015	EMS – all sectors
ISO 22716:2007	Cosmetic GMP
ISO 16128-1/-2:2016/17	Natural-origin % claims
ISO 13485:2016	Medical-device QMS
ISO 22000:2018 / FSSC 22000 v6	Food-safety management
OECD 301 A-F	Ready-biodegradability
CEN EN 17035:2022	Bio-based surfactant spec & tests

