UDC 604:339.1:608 DOI: https://doi.org/10.33730/2077-4893.4.2025.345420

GLOBAL MARKET OF BIOLOGICAL PRODUCTS: TRENDS, CHALLENGES, AND FUTURE OUTLOOK

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Біологічні препарати — біопестициди, біостимулятори та біодобрива — дедалі більше розглядаються як ключові інструменти сталого розвитку агросектору, що дають змогу зменшити застосування хімічних засобів, покращити стан ґрунтів і підвищити стійкість культур до біотичних та абіотичних чинників. Актуальність дослідження зумовлена політичними стратегіями, зокрема «Від лану до столу» Європейського Союзу, яка передбачає скорочення використання пестицидів на 50% та мінеральних добрив на 20–30% до 2030 р. Проведено комплексний мета-аналіз наукових публікацій 2020–2024 рр., галузевих аналітичних звітів та регуляторних документів, що визначають правила реєстрації біологічних продуктів у країнах ЄС та інших юрисдикціях. Отримані результати свідчать про стабільні агрономічні переваги застосування біологічних продуктів, біодобрива забезпечують приріст урожайності в середньому на 12–25%, а біостимулятори підвищують ефективність використання елементів живлення на 9–15% та посилюють стійкість рослин до абіотичних стресів. Однак складність і тривалість реєстраційних процедур для біопестицидів, обмеження переліку дозволених мікроорганізмів у законодавстві ЄС для біостимуляторів, а також відсутність уніфікованих методів оцінки «здоров'я ґрунтів» на сьогодні є основними перешкодами розвитку ринку біопрепаратів. Найбільші труднощі відчувають малі та середні підприємства (МСП), які не мають ресурсів для проходження багаторічних регуляторних процедур, що сприяє ринковій концентрації на користь транснаціональних корпорацій. Для досягнення цілей сталого розвитку необхідна реформа регуляторних систем, гармонізація міжнародних стандартів та впровадження пропорційних до ризику вимог. Перспективи подальших досліджень пов'язані з удосконаленням технологій формуляції біопрепаратів, інтеграцією цифрових інструментів моніторингу та проведенням довгострокових досліджень впливу біологічних продуктів на екосистемні послуги та відновлення ґрунтів.

Ключові слова: *біопестициди, біостимулятори, біодобрива, здоров'я ґрунтів, Європейський зелений курс, стратегія «Від лану до столу», малі та середні підприємства (МСП), бар'єри для інновацій.*

INTRODUCTION

The agricultural sector faces unprecedented challenges in meeting growing food demand while addressing environmental sustainability imperatives [1]. Biological products such as encompassing biocontrol agents, biostimulants, and biofertilizers have emerged as critical tools for sustainable intensification, offering alternatives to synthetic inputs while maintaining or enhancing productivity [2]. This transition is not merely market-driven but mandated by policy frameworks, most notably the European Union's Farm to Fork Strategy, which establishes legally binding targets for pesticide and fertilizer reduction by 2030 [3].

The biologicals market has experienced remarkable growth, with global valuations exceeding USD 10 billion in 2023 and compound annual growth rates (CAGR) of 12–16% across product categories [4]. The biopesticide segment alone demonstrates a CAGR of 16.1% for 2019–2025, while the U.S. biofertilizer market is projected to surpass USD 1 billion by 2029 [5; 6]. This commercial momentum reflects both regulatory pressure and growing recognition of biological products'

potential to address soil health degradation, climate resilience, and sustainable intensification challenges [7].

However, significant barriers persist in translating scientific advances into commercial success. Regulatory frameworks, particularly in developed markets, impose complex, lengthy approval processes that disproportionately affect small and medium-sized enterprises (SMEs). The European Union's dual-tier authorization system, requiring both active substance approval and product-specific registration, can extend market entry timelines to nearly a decade, effectively excluding innovative SMEs from key markets [8].

Analysis of the current state of the global biologicals market through multiple lenses: scientific evidence supporting product efficacy, market dynamics and growth projections, regulatory challenges affecting innovation accessibility, and emerging technological trends likely to shape the sector through 2035 is actual. Particular attention needs to the tension between ambitious sustainability targets and regulatory frameworks that may inadvertently impede the transition they seek to accelerate.

The objective of this review is to analyze the global market of biological products by integrating evidence on scientific efficacy, market growth dynamics, and regulatory frameworks. Special attention is given to the challenges faced by small and medium-sized enterprises (SMEs) under current regulatory systems, as well as to emerging technological innovations likely to shape the sector through 2035.

MATERIALS AND METHODS OF RESEARCH

Literature Search Strategy. We conducted a comprehensive literature review using multiple databases (Google Scholar, PubMed, Web of Science) covering the period 2020–2024. Search terms included combinations of «biological products», «biostimulants», «biocontrol», «biofertilizers», «sustainable agriculture», and «regulatory framework». The search strategy employed both keyword and semantic search approaches to ensure comprehensive coverage of relevant literature.

Market Data Analysis. Market data were compiled from industry reports, regulatory documents, and peer-reviewed publications. We analyzed trends using compound annual growth rate (CAGR) calculations and regional market segmentation. The main sources included market reviews from research of the market companies such as Dunham Trimmer market analyses, Mixing Bowl Hub landscape reports, and official regulatory agency publications.

Regulatory Framework Assessment. Regulatory requirements were analyzed across major jurisdictions in the EU and other parts of the world using official regulatory guidance documents and industry compliance reports. We examined registration timelines, data requirements, and cost implications for different enterprise sizes.

Selection Criteria. We included peer-reviewed articles, government reports, and industry analyses published in English between 2020–2024, focusing on quantitative data and evidence-based assessments. Studies were selected based on methodological rigor, sample size adequacy, and relevance to commercial biological product applications.

RESULTS AND DISCUSSION

Scientific Evidence and Efficacy Data. Quantitative Performance Metrics. Recent meta-analytical studies provide robust evidence for biological product efficacy across diverse agricultural systems. Biofertilizers demonstrate consistent yield improvements of 12–25% compared to untreated controls, with particularly strong effects in nutrient-limited environments [9]. Biostimulants enhance nutrient use efficiency by 9–15% while improving crop tolerance to abiotic stresses including drought, salinity, and temperature extremes [10]. Field trial data from standardized multi-environment studies reveal quantifiable soil health improvements. Three-year trials demonstrate that biostimulant applications increase soil humus content by 1.4–12.8% compared to baseline conditions, while no-till systems combined with biostimulants

raise water-soluble soil carbon by approximately 9.0% versus 2.3% under reduced tillage alone [11].

Mechanistic Understanding and Variability. Despite documented benefits, mechanistic understanding remains incomplete, contributing to variable field performance across environments and cropping systems. Microbial biostimulants, including bacterial and fungal inoculants, show particular sensitivity to indigenous microbiome interactions and environmental conditions, resulting in inconsistent efficacy across locations [12].

Market Dynamics and Growth Projections. Global Market Segmentation. The global biologicals market exhibits strong segmentation across product categories and geographic regions. Dunham Trimmer Market Analysis (2024), that reproduced with data from publicly available market presentation for academic research purposes, demonstrates robust growth across all segments, with biocontrol products representing the largest segment, projected to reach USD 14.5 billion by 2027 with a CAGR ranging from 12.31% to 13.42% (*Fig. 1*) [4].

Biostimulants follow with projections reaching USD 7 billion by 2027, while biofertilizers, though smaller in absolute terms, show the highest growth rate at 13.42% CAGR. This growth pattern reflects increasing recognition of biological products' role in addressing soil health concerns and input cost volatility [17].

Industry Landscape and Corporate Positioning. The Mixing Bowl Hub (2025) developed the comprehensive landscape of crop biostimulant companies, organized by product categories and technological approaches, reproduced from publicly available industry report for academic analysis. The map categorizes companies by product type including microbial extracts, botanical extracts, seaweed extracts, protein hydrolysates, and other specialized categories, demonstrating the diversity and segmentation within the biologicals market (*Fig. 2*).

The landscape reveals significant diversity in technological approaches, with companies positioned across multiple categories including microbial extracts, botanical extracts, seaweed derivatives, protein hydrolysates, and specialized nutrient-cycling inoculants. This segmentation reflects both market opportunities and complex regulatory challenges facing different product categories [13].

Regulatory Framework Analysis. European Union Regulatory Complexity. The European Union's regulatory framework creates significant barriers for biological product commercialization. EU Regulation 2019/1009 establishes classification challenges for bacterial products, as definitions and permitted claims differ between the categories of fertilizers, biostimulants and plant protection products [14]. The two-tier authorization system requires both active substance approval and product-specific authorization, creating duplicative data requirements and extended timelines approaching 10 years for novel products [8].

Biostimulants and Biofertilizers Regulatory Pathways. In the European Union, biostimulants and microbial fertilizers follow a partially distinct regulatory trajectory compared to biocontrol products. Until recently, most microbial biostimulants could only be registered at the national level, often under categories such as plant aids, soil conditioners, or microbial fertilizers. Mutual Recognition mechanisms have provided opportunities for cross-border market access; however, certain Member States, including Romania, Hungary, and France, apply restrictive policies that limit recognition of foreign registrations.

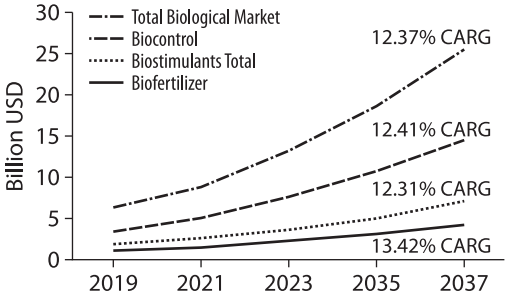

Chart does not include Speciality Nutrition market

Fig. 1. Global Biological Market Evolution (2019–2027)

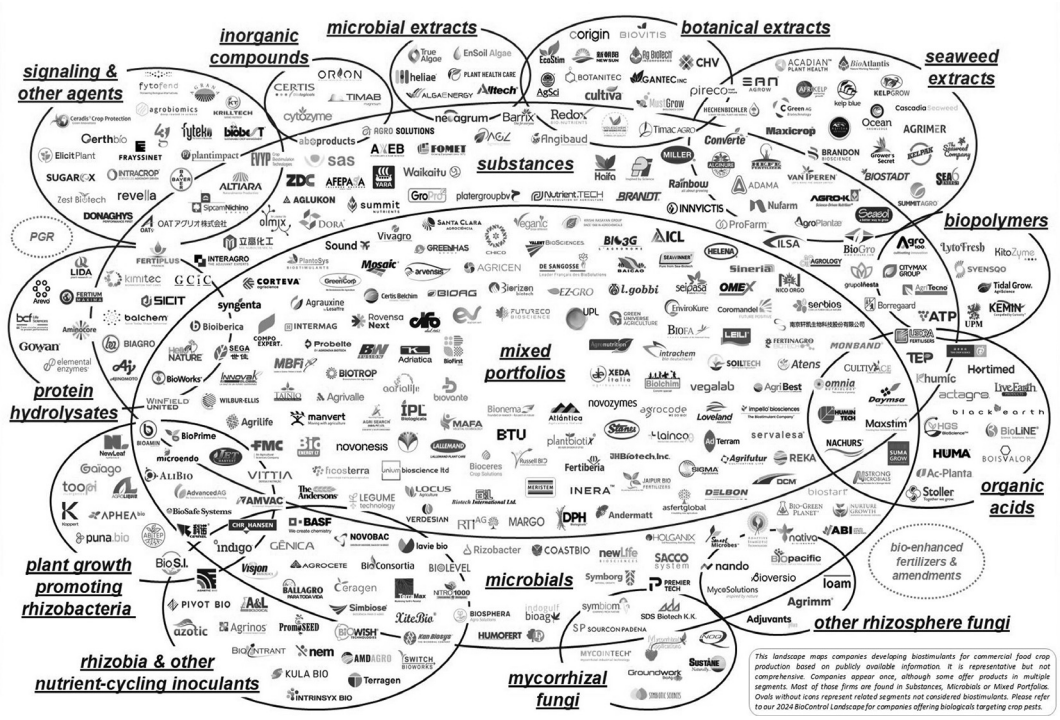

Fig. 2. Comprehensive overview of agricultural biostimulants companies and segmentation of crop biostimulants (2025) [13]

The adoption of Regulation (EU) 2019/1009 on EU Fertilising Products introduced a harmonized pathway for biostimulants at the EU level. Nevertheless, the regulation currently permits only a narrow set of microbial taxa — specifically *Azotobacter* spp., *Azospirillum* spp., *Rhizobium* spp., and arbuscular mycorrhizal fungi (*Glomus* spp.) — to be used in EU-labelled microbial fertilizers. Expansion beyond this limited list requires regulatory updates.

Ongoing discussions within the European Commission and expert working groups focus on developing science-based criteria to include additional microbial strains. However, substantial revisions are not expected before 2027, leaving many innovative microbial biostimulants outside the harmonized framework in the near term. This regulatory lag slows innovation diffusion and disproportionately affects SMEs seeking EU-wide market access [14].

SME-Specific Market Access Barriers for Biopesticides. Small and medium-sized enterprises face disproportionate regulatory burdens that effectively exclude them from major markets. Regulatory costs can exceed USD 1–5 million per product for comprehensive dossiers, representing prohibitive investments for companies with limited resources [15]. Extended approval timelines compound these challenges by delaying revenue generation and increasing financial risk.

Technological Innovation Trends. Advanced Formulation Technologies. Formulation remains one of the most critical bottlenecks for the widespread commercialization of biological products. Many companies continue to rely on first-generation liquid formulations, which typically provide only limited shelf life and moderate field stability. Although effective in controlled conditions, their variability under diverse environments restricts farmer confidence and adoption.

Industrial research has explored microencapsulation technologies, which can extend microbial viability and allow controlled release. However, these methods are often expensive, difficult to scale, and therefore remain limited to niche products. Other approaches, such as spray drying and lyophilization, offer industrial feasibility but are only applicable to a narrow range of microbial species.

Formulation innovation addresses critical commercialization bottlenecks including shelf-life limitations and environmental stability. Encapsulation technologies using biopolymer matrices and controlled-release systems extend microbial viability to three months or longer, addressing critical shelf-life limitations that have historically constrained biological product adoption.

As a result, there is a clear market demand for stable, efficient, and cost-effective formulations that can maintain microbial efficacy during storage, transport, and field application. Continuous innovation in carriers, protective agents, and formulation processes is expected to remain a central research focus in the coming years [16–20].

From Mechanistic Research to Field-Relevant Evidence. Beyond formulation, another important frontier lies in strengthening the scientific evidence base for biologicals. While a large body of highly specific academic research exists — often at the molecular or physiological level — there is a relative scarcity of generalized, field-relevant datasets that demonstrate consistent impacts on soil health, crop productivity, and stress resilience.

Current challenges include the difficulty of defining and measuring soil health, as well as linking laboratory findings with practical farm-scale outcomes. Even when products demonstrate, promising results in trials, the mechanisms of action frequently remain only partially understood, limiting their acceptance in regulatory frameworks.

With more systematic research, meta-analyses, and cross-environment datasets, the industry will gain a more precise and consistent approach to biological product use. This integration — combining detailed mechanistic insights with large-scale, field-validated evidence — will be crucial for building farmer trust, supporting regulatory dossiers, and accelerating mainstream adoption.

Evidence Base and Practical Implementation Gaps. The accumulated scientific evidence demonstrates that biological products deliver significant agronomic benefits across diverse cropping systems. Meta-analytical studies consistently report yield improvements of 12–25% with biofertilizers and nutrient-use efficiency gains of 9–15% with biostimulants [9; 10]. These findings are corroborated by large-scale industry datasets, including systematic commercial trials spanning multiple crop groups and geographic regions, which independently confirm yield increases exceeding 10% under practical farming conditions.

However, aggregate performance metrics mask substantial field-to-field variability driven by soil characteristics, environmental conditions, indigenous microbiome composition, and agronomic management. This variability represents the sector's most critical challenge: while biologicals consistently demonstrate positive effects in controlled meta-analyses, individual farmer experiences may diverge significantly from expected outcomes. The problem lies not in insufficient efficacy data but in the absence of standardized testing protocols, predictive models for environment-specific performance, and universally accepted metrics for soil health improvement.

Addressing these gaps requires several complementary approaches. They could include such ones. First, the establishment of standardized multi-environment testing protocols that enable cross-study comparisons and meta-analytical synthesis is necessary. Second, the development of diagnostic tools, including NDVI imaging, drone-based monitoring, and microbiome profiling platforms such as BIOTREX and Biome Makers that enable real-time performance validation and adaptive management recommendations. Third, the integration of omics-technologies to identify molecular markers associated with efficacy, enabling both mechanistic understanding and environment-specific product selection.

The transition from promising laboratory results to consistent field performance thus depends less on additional proof-of-concept studies than on systematic evidence generation at scales relevant to commercial agriculture.

Regulatory Frameworks as Innovation Bottlenecks. Market projections indicate robust growth potential, with compound annual growth rates of 12–13% across biological product categories driven by policy mandates and farmer demand for sustainable alternatives. Yet regulatory complexity systematically constrains this potential, creating a paradox wherein ambitious sustainability targets coexist with approval systems that impede the innovations necessary to achieve those targets.

The European Union's regulatory politic exemplifies these contradictions. For biocontrol products, Regulation (EC) No 1107/2009 establishes a two-tier authorization system requiring both active substance approval and product-specific registration. This process imposes timelines approaching ten years and costs that according to industry estimates reach several million Euros per product [15]. For biostimulants and microbial fertilizers, Regulation (EU) 2019/1009 created a harmonized pathway but with severely restricted scope: only four microbial genera (*Azotobacter*, *Azospirillum*, *Rhizobium*, and arbuscular mycorrhizal fungi) currently qualify for EU-wide registration as microbial fertilizers. Expansion of this list remains under discussion but is not anticipated before 2027, leaving most innovative microbial products confined to fragmented national registration systems where Mutual Recognition is applied inconsistently, particularly in restrictive markets such as Romania, Hungary, and France.

These barriers disproportionately affect small and medium-sized enterprises, which lack the regulatory expertise, capital reserves, and product portfolios to absorb extended approval timelines and duplicative data generation costs. The result is market consolidation favoring established multinationals capable of navigating regulatory complexity, while innovative SMEs, which are often the source of technological innovations, face effective exclusion from key markets.

International associations including IBMA, EBIC, and IBPA have advocated for regulatory harmonization and streamlined approval pathways for two decades. While these efforts have yielded incremental improvements, the fundamental structure remains prohibitively complex for most SMEs. More importantly, the regulatory lag between scientific innovation and market authorization creates a temporal mismatch: by the time novel biologicals complete registration, market conditions, agronomic challenges, and competitive landscapes may have shifted substantially.

Beyond Europe, this regulatory model exerts global influence. Many OECD countries and markets influenced by EU standards — including Morocco, Kenya, and South Africa — effectively require prior EU or OECD registration as a prerequisite for domestic approval. This regulatory cascading amplifies the EU system's SME-exclusionary effects across multiple continents, limiting farmer access to biological innovations precisely in regions where climate challenges and soil degradation create the most urgent need for sustainable intensification tools.

Policy Reform Imperatives. Achieving the European Union's Farm to Fork Strategy targets, which include 50% reduction in chemical pesticide use and 20–30% reduction in fertilizer use by 2030, requires policy coherence between sustainability ambitions and regulatory enablement [3]. Current frameworks create structural contradictions that undermine stated objectives by restricting access to the very tools needed for chemical input substitution. Priority reforms should address such critical dimensions as regulatory harmonization across jurisdictions to eliminate duplicative testing requirements and enable mutual recognition of safety assessments (International standards developed through organizations such as OECD would reduce the burden of multiple national submissions while maintaining appropriate safety oversight); risk-proportionate data requirements

that match regulatory stringency to product risk profiles (low-risk biologicals with established safety records should face expedited pathways rather than requirements designed for novel synthetic chemistry); SME-specific approval mechanisms including tiered data packages, extended proprietary protection periods to justify investment, and technical assistance programs that democratize regulatory navigation.

The biostimulant and biofertilizer regulatory pathway offers a model for accelerated reform. Expanding the approved microbial genera list beyond the current four taxa, establishing clear criteria for inclusion of new strains based on risk assessment rather than arbitrary restrictions, and harmonizing national registration systems would substantially accelerate innovation diffusion. These measures need not compromise safety; rather, they would align regulatory procedures with the lower risk profiles that distinguish biological products from synthetic chemistry.

Without such reforms, the Farm to Fork Strategy's ambitious targets risk becoming aspirational rhetoric rather than achievable objectives. The gap between policy intention and regulatory reality creates a credibility challenge that undermines stakeholder confidence in sustainability transitions.

Technological Trajectories and Industry Evolution. The sector's future development will be shaped by advances across three interconnected domains: formulation technologies, scientific evidence of integration systems, and digital agriculture platforms.

Formulation innovation addresses the sector's most persistent commercialization bottleneck. Many current products rely on first-generation liquid formulations with limited shelf life and environmental stability, constraining distribution infrastructure and farmer adoption. While microencapsulation technologies using biopolymer matrices offer promising pathways to extended viability — potentially achieving shelf lives exceeding three months — these approaches remain expensive and difficult to scale [16–20]. Industrial techniques including spray drying and lyophilization provide manufacturability but apply to limited microbial species. The development of cost-effective, widely applicable stabilization technologies represents a critical enabling requirement for market expansion, particularly in distribution-challenged regions.

Evidence-based integration systems will determine the sector's credibility trajectory. The current evidence base, while demonstrating aggregate efficacy, lacks the standardization and environmental specificity needed for precision application recommendations. Future advances depend less on additional laboratory proof-of-concept studies than on systematic, multi-environment field trials that generate predictive models for product-by-environment interactions. Integration of real-time diagnostic tools — foliar analysis, NDVI monitoring, soil microbiome profiling — with machine learning algorithms can transform biologicals from inputs applied on faith to precision tools deployed based on measured soil-plant-microbe status.

Digital agriculture convergence represents the sector's most transformative potential. Artificial intelligence platforms that integrate trial data, environmental monitoring, and agronomic management can optimize application timing, predict performance, and enable adaptive management strategies. Start-ups specializing in AI-based diagnostics and decision support systems are increasingly acquisition targets for multinationals seeking to differentiate commodity biologicals through data-enhanced value propositions. This convergence of biotechnology, agronomy, and data science signals the sector's evolution from product-centric to system-solution business models.

These technological trajectories will unfold against a backdrop of continued industry consolidation. Large corporations will likely continue acquiring innovative SMEs and specialized technology platforms, leveraging scale advantages in regulatory navigation, distribution infrastructure, and market access. However, the sector's innovation vitality depends on maintaining a diverse ecosystem where niche SMEs can develop novel formulations, target specialty crops, and create

diagnostic-integrated services before potential acquisition. Regulatory frameworks that facilitate rather than impede SME market entry thus serve not only equity objectives but also innovation sustainability.

Limitations and Future Research Directions. This review has several limitations that warrant acknowledgment. First, the market data synthesis relies heavily on industry reports rather than peer-reviewed economic analyses, reflecting the paucity of academic attention to biologicals market dynamics. Second, regulatory analysis focuses primarily on European and OECD systems, with limited coverage of rapidly evolving frameworks in LATAM and Asia-Pacific regions that may offer alternative models. Third, the efficacy evidence reviewed, while extensive, derives predominantly from biofertilizer and biocontrol categories, with biostimulants remaining less thoroughly documented in peer-reviewed literature.

Future research should prioritize several critical gaps. Among them the systematic meta-analyses examining moderators of biological product efficacy- particularly soil properties, climate variables, and management interactions — would enable environment-specific recommendations. In addition, economic analyses comparing total cost-of-ownership for biological versus conventional input systems, accounting for soil health improvements and long-term sustainability benefits, would strengthen adoption business cases. Moreover, comparative regulatory analyses examining approval efficiency, safety outcomes, and innovation rates across different jurisdictional frameworks would inform evidence-based policy reform. Finally, longitudinal studies documenting soil microbiome shifts, carbon sequestration, and ecosystem service provision under biological product regimes would quantify sustainability benefits beyond immediate yield effects.

CONCLUSIONS

The global biologicals market represents a critical pathway toward sustainable agriculture, supported by robust scientific evidence and driven by policy imperatives including the EU's Farm to Fork Strategy. The market analysis demonstrates significant growth potential, with projections indicating expansion from USD 10 billion in 2023 to USD 25+ billion by 2027, driven by CAGRs exceeding 12% across all product categories.

However, regulatory frameworks create substantial barriers to innovation and market access, particularly for SMEs that drive sector innovation. The current system's complexity, exemplified by EU registration timelines approaching 10 years and duplicative data requirements, contradicts policy objectives by impeding the innovations needed to achieve sustainability targets.

The industry landscape reveals a diverse ecosystem of companies employing varied technological approaches, yet regulatory barriers may consolidate this diversity into fewer, larger players with regulatory resources. This consolidation risks reducing innovation potential and limiting farmer access to biological tools.

Future success in biologicals depends on regulatory reform that democratizes access to innovation while maintaining appropriate safety standards. This requires harmonized international frameworks, SME-specific approval pathways, and risk-proportionate data requirements that match the urgency of sustainability imperatives.

The transition to sustainable agriculture is not merely a technical challenge but a systemic transformation requiring aligned policies, accessible innovations, and supportive market frameworks. The biologicals sector offers proven tools for this transition, but unlocking their full potential requires regulatory evolution that matches the urgency of global sustainability challenges.

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Стаття надійшла до редакції журналу 24.10.2025