

Regulatory Barriers and Global Adoption of Melanin-Enhanced Bt Biopesticides: An Environmental Sociology Perspective

CHEN, Meizhen

Nord Anglia Chinese International School Shanghai, China

As global demand for sustainable agriculture rises, biopesticides represented by *Bacillus thuringiensis* (Bt) have become a core alternative to chemical pesticides. However, UV-induced photodegradation severely limits the field efficacy of conventional Bt products. Melanin-enhanced Bt, a genetically modified microbial (GMM) formulation with improved photostability, offers a technical solution, yet it faces divergent regulatory barriers across major economies that hinder its global adoption. Taking the United States, the European Union, China, and Brazil as research subjects, this paper systematically compares their regulatory frameworks for melanin-enhanced Bt, analyzes the structural drivers of regulatory divergence from four dimensions—political philosophy, economic interests, historical memory, and international trade regimes—and proposes targeted policy recommendations at global, national, and industrial levels.

Keywords: Bt biopesticide, melanin, genetically modified microorganism, regulatory divergence, global governance

Introduction

Research Background

Against the backdrop of the United Nations 2030 Sustainable Development Goals, food security and agricultural sustainability have become global policy priorities. Pest infestations and pesticide overuse remain the two primary threats to stable crop yields and ecological health at the production level.

According to the Food and Agriculture Organization (FAO, 2023), global agricultural pesticide use reached 3.70 million tonnes in 2022, doubling the volume recorded in 1990. Synthetic chemical pesticides dominate the global market, as farmers rely on their rapid efficacy to maintain yields. However, decades of research have confirmed their severe environmental externalities: less than 1% of applied active ingredients reach target pests, while the remainder accumulates in soil, contaminates groundwater, disrupts soil microbiomes, and bioaccumulates through the food chain, posing chronic risks to ecosystems and human health (Ganai, Khan, & Tabasum, 2018).

In response, major economies have introduced policies to reduce chemical pesticide reliance. The European Commission proposed a 50% reduction target for chemical pesticide use and risk in 2020; China has promoted biological and physical pest control through central government subsidies, achieving a 17.2% drop in pesticide use between 2015 and 2020. Driven by regulatory incentives and growing consumer demand for residue-free agricultural products, the global biopesticide market is projected to nearly double between 2025 and 2030 (Markets and Markets, 2026).

CHEN, Meizhen, Nord Anglia Chinese International School Shanghai, China.

Among all biopesticides, *Bacillus thuringiensis* (Bt) is the most widely adopted, with over 40 years of application in forestry, crop production, and vector control. Its Cry insecticidal proteins exhibit high target specificity and negligible impacts on non-target organisms, making it the flagship model for biological pest control. Despite these advantages, chemical pesticides still hold 72% of the global crop protection market. A key technical bottleneck limiting Bt's large-scale deployment is its rapid inactivation under ultraviolet (UV) radiation, which shortens field efficacy duration and increases application frequency.

To address this gap, this paper focuses on melanin-enhanced Bt, a novel formulation that leverages the natural UV-absorbing properties of melanin to protect Bt proteins from photodegradation.

Research Question and Scope

The advancement of melanin-enhanced Bt reveals a critical policy paradox: scientifically validated, environmentally beneficial biotechnological innovations consistently struggle to penetrate global markets. The barrier lies not only in technical limitations, but also in divergent regulatory philosophies and institutional frameworks across nations.

This paper moves beyond a purely comparative legal analysis to conduct a public policy analysis of four major agricultural economies: the United States, the European Union, China, and Brazil. Its core research question is: taking melanin-enhanced Bt as a case study, what structural factors drive regulatory divergence that impedes the global adoption of innovative biopesticides?

Paper Structure

The remainder of this paper is organized as follows: Section 2 outlines the scientific background of melanin-enhanced Bt, including its mechanism, benefits, and risks. Section 3 systematically compares the regulatory frameworks of the four economies. Section 4 analyzes the structural drivers of regulatory divergence. Section 5 discusses the implications for developing economies and core stakeholders. Section 6 proposes targeted policy recommendations. Section 7 concludes the paper.

Scientific Background of Melanin-Enhanced Bt

Bt Biopesticides: Mechanism and Safety Profile

Commercial Bt biopesticides are sprayable formulations consisting of dried Bt spores, insecticidal crystalline proteins, and inert ingredients. The primary active components, Cry and Cyt toxins, are δ -endotoxins produced as parasporal crystals by the Gram-positive *Bacillus thuringiensis* bacterium.

Upon ingestion by susceptible pest larvae, these protoxins are activated in the alkaline midgut, bind to specific epithelial receptors, disrupt cell membrane integrity, and cause lethal septicemia. This receptor-dependent mode of action underpins Bt's extreme target specificity: it is only effective against Lepidoptera, Coleoptera, and Diptera larvae, while mammals including humans lack corresponding gut receptors. Bt proteins degrade rapidly in the acidic mammalian digestive tract, and acute and chronic toxicity studies have consistently found no adverse health effects at relevant exposure levels (Schlessinger, Rahimi, & Schlessinger, 2025).

Notably, this paper focuses exclusively on sprayable Bt formulations, not plant-incorporated protectants (PIPs) expressed in transgenic crops. The melanin-enhanced Bt analyzed in this paper is classified as a genetically modified microorganism (GMM): the Bt strain is engineered to endogenously synthesize melanin, which co-localizes with spores and Cry proteins to provide UV protection. This genetic modification is the defining feature shaping its regulatory classification worldwide.

Rationale for Melanin Modification

Melanin is a ubiquitous natural pigment produced by nearly all living organisms, synthesized from the amino acid tyrosine. Its core biological function is to shield cells from UV radiation and oxidative stress by absorbing and dissipating harmful wavelengths.

UV-induced photodegradation is the single largest limitation of field-applied Bt products. Simulated solar irradiation has been shown to degrade up to 35% of tryptophan residues in Bt crystal proteins, directly reducing insecticidal activity (Pusztai et al., 1991). Melanin's strong UV-absorbing capacity enables it to protect Bt proteins from photooxidative damage without altering their mode of action.

From a safety perspective, natural melanin has an extremely low toxicity profile. As a high-molecular-weight biopolymer, it is not absorbed by the human gastrointestinal tract after ingestion; it passes through the digestive system and is excreted intact, without entering the bloodstream or causing pigmentation effects.

Potential Benefits

The melanin-enhanced formulation delivers three categories of value:

1. Environmental benefits: Both Bt proteins and melanin are naturally occurring substances that degrade without persistent toxic residues. Pests develop resistance to biopesticides far more slowly than to chemical products, and the formulation's sustained release profile better supports beneficial insect populations and farmland biodiversity.

2. Agronomic efficiency: Melanin improves Bt photostability by a factor of 9.7 while enhancing biological activity. This allows farmers to spray during normal daylight hours instead of only in the evening or on overcast days, reducing labor scheduling costs and operational unpredictability. Melanin also acts as a biostimulant, with documented yield increases of 20-40% in certain crop systems (Avetisyan et al., 2024).

3. Supply chain and equity value: The formulation exhibits slower activity decay during storage and transport, extending shelf life and strengthening supply chain stability. These improvements lower adoption barriers for smallholder farmers in developing economies and indirectly reduce carbon emissions from repeated field applications.

Potential Risks and Limitations

Melanin-enhanced Bt also faces technical, practical, and regulatory risks:

1. Technical and practical limitations: R&D and industrial-scale production remain in early stages, requiring substantial infrastructure investment. Bt application requires specialized training and strict adherence to timing protocols, raising operational costs. Its narrow target spectrum means farmers may still need complementary products for broad-spectrum control, and its slow mode of action requires preventive rather than curative application.

2. Regulatory and safety concerns: As a GMM product, it is subject to strict safety evaluations worldwide. Regulators commonly raise concerns including risks of horizontal gene transfer (HGT) to native soil microbes, the presence of antibiotic resistance markers (ARGs) in engineering strains, and long-term environmental fate data gaps. Melanin itself raises debated concerns about environmental persistence as an extremely stable biopolymer that may accumulate in soil ecosystems.

Comparative Regulatory Frameworks Across Major Economies

This section compares regulatory pathways for melanin-enhanced Bt across four economies, structured consistently around regulatory architecture, rules for wild-type Bt, classification of the melanin-enhanced formulation, and approval timeline and barriers.

United States

Regulatory architecture. The U.S. governs biotechnology under the Coordinated Framework for Regulation of Biotechnology (established 1986, updated 2017), which regulates products through existing statutes administered by three lead agencies: the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA, 2023).

For Bt pesticides, primary regulatory authority rests with the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Food Quality Protection Act (FQPA), and the Pesticide Registration Improvement Extension Act. All pesticide products must obtain EPA registration and establish food residue tolerances (or exemptions) before entering the market (U.S. Environmental Protection Agency, 2021). The USDA's Animal and Plant Health Inspection Service (APHIS) regulates the interstate movement and environmental release of genetically engineered microbial pesticides.

Regulation of wild-type Bt. Wild-type Bt is classified as a low-risk microbial pesticide and qualifies for substantial regulatory flexibility. The EPA offers an expedited review pathway with simplified data requirements, lower fees, and shorter timelines than conventional synthetic pesticides. Products with an established history of safe use may be exempt from full toxicological studies. New conventional biopesticides typically receive registration in less than one year, compared to three or more years for chemical pesticides. In 2025, the EPA further streamlined re-registration procedures for low-risk biopesticides.

Regulatory pathway for melanin-enhanced Bt. Melanin-enhanced Bt is classified as a genetically engineered microbial pesticide, not a plant-incorporated protectant (PIP). Because it involves genetic modification, it is ineligible for the full exemptions and streamlined pathways available to wild-type Bt.

Market entry requires compliance with overlapping regimes: applicants must satisfy both USDA-APHIS ecological risk assessment requirements under 7 CFR Part 340 and EPA registration requirements under 40 CFR Part 172. This multi-agency review is further complicated by independent state-level pesticide registration rules.

Timeline and core barriers. Genetically modified microbial pesticides typically require 1.5-2.5 years for full approval. The primary barriers are jurisdictional ambiguity across federal agencies and states, duplicated data submission requirements, and elevated compliance costs from fragmented oversight.

European Union

Regulatory architecture. The EU maintains the strictest regulatory regime among the four economies. Oversight is split between the European Food Safety Authority (EFSA), which conducts independent scientific risk assessments, and the European Commission, which manages risk governance and makes final approval decisions. All pesticide products are subject to mandatory environmental risk assessment (ERA), and EFSA sets legally binding maximum residue levels (MRLs) for all approved active substances (European Food Safety Authority, n.d.).

Regulation of wild-type Bt. Wild-type Bt used as a plant protection product (PPP) is regulated under Regulation (EC) No 1107/2009 (EUR-Lex, 2009). Microbial pesticides qualify for reduced data requirements under this framework, but the process remains rigorous: active substances are approved at the EU level for a maximum 10-year term, subject to full re-evaluation upon expiry.

Regulatory pathway for melanin-enhanced Bt. The EU does not draw a legal distinction between genetically modified microbial pesticides and other GMOs. As a result, melanin-enhanced Bt falls fully within

the scope of Directive 2001/18/EC on the deliberate release into the environment of GMOs (EUR-Lex, 2001).

This classification triggers the EU's strict GMO approval framework. Authorization requires a positive scientific opinion from EFSA, but even a favorable opinion does not guarantee approval: the European Commission frequently fails to secure the required qualified majority in the Appeal Committee, leaving products in prolonged regulatory limbo. Even after EU-level approval, products must undergo additional national-level scrutiny, as many member states maintain independent GMO restrictions.

Timeline and core barriers. Conventional microbial pesticides typically take 2.5-3.5 years to approve. For genetically modified microbial pesticides like melanin-enhanced Bt, the timeline extends to 5 years or more, with high risk of ultimate rejection due to political opposition rather than scientific assessment. Core barriers include the precautionary principle applied to all GMOs, highly politicized risk management, and fragmented national implementation rules.

China

Regulatory architecture. China's pesticide regulation is centrally administered by the Ministry of Agriculture and Rural Affairs (MARA). The national policy framework explicitly encourages safe, efficient biopesticides while accelerating the phase-out of high-risk products. The 14th Five-Year Plan for National Agricultural Green Development identifies biopesticide development as a core priority.

Regulation of wild-type Bt. Wild-type Bt qualifies for reduced registration requirements set by the Institute for the Control of Agrochemicals under MARA. Biopesticides benefit from shorter efficacy trials (on average one year less than chemical pesticides) and registration costs equal to only 5-20% of those for chemical products.

As of 2026, 179 biopesticide active ingredients have been approved in China, encompassing 2,800 end-use products. By variety count, China ranks second globally, with microbial pesticides representing the largest category (Ministry of Agriculture and Rural Affairs of China, 2026). Full registration for wild-type Bt typically takes 1.5-2.5 years.

Regulatory pathway for melanin-enhanced Bt. Melanin-enhanced Bt is classified as an agricultural product processed from genetically modified microorganisms, requiring safety evaluation by the National Agricultural GMO Safety Committee under MARA. The Committee holds at least two formal evaluation sessions per year.

Genetically modified microbial products face longer review cycles and lower approval rates than transgenic plant varieties, and regulatory guidance for this category remains less detailed. Once the formal process is initiated, however, China's review timeline is among the shortest of major economies, in part because regulators may reference prior safety data from jurisdictions such as the United States. Pesticide registration certificates are valid for five years.

Core barriers. The primary barriers are political sensitivity and policy ambiguity, not procedural speed. China's food security strategy prioritizes staple grain self-sufficiency, and GMO products remain politically sensitive due to moderate public acceptance. Regulators must assess whether transgenic product approvals could trigger widespread public anxiety, creating an inherent tension: biopesticides are strongly encouraged, but those incorporating transgenic technology remain subject to strict supervision.

Brazil

Regulatory architecture. Brazil is the world's second-largest adopter of genetically modified crops and has the fastest-growing pesticide sector among the four economies. Its biosafety system is centered on the

National Technical Commission on Biosafety (CTNBio), established under Law No. 11.105/05. Composed of 54 PhD-level specialists, CTNBio issues legally binding technical decisions on GMO safety, analogous to EFSA’s role in the EU. Final market registration and enforcement fall to ANVISA, the national health surveillance agency.

Regulation of wild-type Bt. Wild-type microbial biopesticides follow a highly streamlined pathway. The average approval time for biopesticides is just 14.5 months, compared to 63.4 months for chemical pesticides. In 2025, Brazil approved 912 pesticide products, with biopesticide registrations increasing by 53% year-over-year (AgroLatam, 2025).

Regulatory pathway for melanin-enhanced Bt. Brazil applies a dual framework covering both microbial pesticide rules and GMO biosafety requirements, but two features make its system far more efficient.

First, the 2024 Bioinputs Law (Law No. 15.070/24) moved all biological inputs into a dedicated full-cycle regulatory system separate from conventional pesticides (Demarest Law, 2024). Second, CTNBio has continuously streamlined GMO approval procedures: new breeding technologies without foreign genetic material are exempt from GMO-level regulation, and risk assessment focuses on trait-based mode of action to reduce redundant materials.

Brazil also maintains formal international coordination mechanisms, incorporating foreign preliminary assessment data into its own reviews to eliminate redundant testing.

Timeline and core barriers. For genetically modified microbial biopesticides, total approval time typically falls between 1.5 and 2.5 years, comparable to the United States and significantly faster than the EU. The centralized authority of CTNBio avoids the political tug-of-war between technical assessment and administrative decision-making seen in China and the EU. The primary barrier is the full-cycle compliance requirement under the Bioinputs Law, which adds production and waste disposal oversight.

Cross-Jurisdictional Comparison Summary

Dimension	United States	European Union	China	Brazil
Lead agencies	EPA, USDA-APHIS, FDA	EFSA, European Commission	MARA, National Agricultural GMO Safety Committee	CTNBio, ANVISA
Wild-type Bt timeline	< 1 year	2.5-3.5 years	1.5-2.5 years	~14.5 months
Melanin-Bt classification	Genetically engineered microbial pesticide	GMO under Directive 2001/18/EC	Agricultural GMM product	GMM under Bioinputs Law
GMM approval timeline	1.5-2.5 years	5+ years (high rejection risk)	2-3 years	1.5-2.5 years
Core principle	Risk-benefit balance	Precautionary principle	Food security + prudent supervision	Export competitiveness + efficiency
Jurisdiction risk	High (federal + state)	Medium (EU + member states)	Low (centralized)	Low (binding technical decisions)

Drivers of Regulatory Divergence

The stark differences in regulatory frameworks cannot be explained by technical safety differences alone. They arise from four interconnected structural factors.

Divergent Political Philosophies

The deepest source of divergence lies in competing regulatory philosophies.

The United States adheres to an innovation-driven principle grounded in risk-benefit balancing. Under FIFRA, a pesticide may be restricted only if it poses “unreasonable adverse effects on the environment”, a standard that explicitly weighs economic, social, and environmental costs and benefits (Cropper, Evans, & Portney, 1991). The underlying assumption is that technological innovation should be permitted unless proven to cause disproportionate harm.

The European Union operates under the precautionary principle: when a pesticide poses plausible but uncertain risks, authorities may restrict or ban it to prevent potential harm, even without conclusive scientific evidence. While this approach reduces the cost of removing hazardous products, it also suppresses innovation by exposing novel biopesticides to unpredictable administrative sanctions.

China balances two competing priorities: food security and prudent risk governance. The state actively promotes biopesticides for green agricultural transition, but transgenic technology remains politically sensitive, leading to a system with fast procedural execution but conservative eligibility criteria for GMM products.

Brazil’s philosophy is explicitly growth- and export-oriented. It maintains rigorous technical safety assessment but rejects the precautionary principle’s bias against innovation, aligning closely with the U.S. model of risk-based, science-centered regulation.

Structural Economic Interests

Regulatory approaches also reflect each jurisdiction’s structural economic interests.

The U.S. system is strongly industry-influenced, with economic cost-benefit analysis embedded in regulatory decision-making by law. This benefits its large domestic agrochemical and biotechnology sector and supports the competitiveness of U.S. agricultural exports, though critics argue it weakens health and environmental oversight.

The EU system is largely public- and NGO-driven, with consumer opinion and environmental groups exerting strong influence. This focus on consumer protection has come at a measurable cost: between 2017 and 2024, the number of plant protection tools available to EU farmers declined by 22%, with alternatives failing to keep pace with withdrawals. European farmers have lost competitive ground relative to their U.S. counterparts, and high compliance costs for novel products are ultimately passed to small-scale operators (Euractiv, 2024).

China’s economic incentives center on domestic food security and input self-sufficiency. Biopesticide development is supported to reduce reliance on imported chemical pesticides, but transgenic product benefits are weighed against the social cost of public backlash.

Brazil’s economic interests are straightforward: as a leading global agricultural exporter, faster approval of yield-enhancing technologies directly translates to export revenue and global market share.

Historical Memory and Public Trust

Public trust in agricultural biotechnology, shaped by historical food safety events, is a powerful driver of regulatory stringency.

The EU’s cautious stance towards GMOs is deeply rooted in the 1980s-1990s bovine spongiform encephalopathy (BSE) crisis. The British government’s initial false assurances that BSE could not transmit to humans eroded public confidence in official scientific claims. Subsequent crises including dioxin contamination, foot-and-mouth disease, and listeriosis reinforced this distrust, fostering widespread public skepticism of agricultural biotechnology (Pew Initiative on Food and Biotechnology, 2005). This legacy led to a de facto GMO approval moratorium from 1998 to 2004 and continues to shape policy today.

The United States has never experienced a comparable domestic food safety crisis linked to agricultural biotechnology, and its cultural orientation towards innovation has fostered relatively higher public trust.

China's public attitudes towards GMOs are ambivalent. While there is no single defining crisis equivalent to BSE, periodic media controversies have shaped public discourse, leading regulators to adopt a cautious approach to avoiding social unrest.

Brazil has not experienced a major national food safety crisis linked to biotechnology. Decades of widespread commercial GMO cultivation have built high public acceptance, creating a supportive social environment for biopesticide innovation.

Fragmented International Trade Regimes

The global regulatory landscape is further fragmented by competing international legal regimes.

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) requires trade restrictions to be based on scientific risk assessment, prioritizing open trade. This framework aligns closely with the U.S. risk-based model and does not recognize the precautionary principle as a valid basis for permanent trade barriers (Gruszczynski & Scott, 2023).

The Cartagena Protocol on Biosafety (2000) embodies the EU's precautionary approach. It regulates transboundary movement of Living Modified Organisms (LMOs) and grants importing countries the right to refuse LMO imports on biosafety grounds, even in the absence of conclusive scientific evidence of harm. Over 150 countries are parties to the Protocol.

The landmark 2006 EC-Biotech dispute resolved this tension in practice: the WTO panel ruled against the EU's de facto GMO moratorium, finding that its approval delays and national bans were not based on valid risk assessment as defined by the SPS Agreement. The panel declined to give legal weight to the Cartagena Protocol's precautionary approach, establishing that WTO rules take de facto precedence in trade disputes.

For melanin-enhanced Bt, this fragmented regime means a product approved in one country may be blocked in another under a different legal framework. Countries including China and Brazil bear high dual compliance costs to satisfy both WTO obligations and Cartagena Protocol requirements.

Broader Implications

The Role of Developing Economies

Developing economies occupy a unique position: they stand to gain the most from melanin-enhanced Bt, yet face the greatest barriers to adoption.

For most low- and middle-income countries, food security and smallholder livelihoods are overriding priorities. Smallholder farmers often rely on inexpensive, highly toxic chemical pesticides due to limited access to alternatives and technical knowledge. Conventional Bt's UV instability and short shelf life make it poorly suited to remote rural areas with limited cold chain infrastructure. Melanin-enhanced Bt, with extended field efficacy and improved shelf stability, addresses many of these practical limitations and aligns well with smallholder production systems.

However, most developing countries lack the regulatory capacity to evaluate novel GMM biopesticides independently. Many have no dedicated biosafety framework or standardized risk assessment protocols, and they lack laboratory infrastructure to generate local efficacy data.

Brazil offers an instructive model for middle-income countries. By building a technically competent, centralized biosafety authority and aligning its review processes with international partners, Brazil has achieved

approval speeds comparable to high-income economies while maintaining safety standards. For least developed countries, international organizations such as the FAO and WHO play a critical role in building regulatory capacity. Ultimately, equitable global adoption will require targeted investment in regulatory capacity and smallholder extension services in the Global South.

Stakeholder Analysis

The global deployment of melanin-enhanced Bt involves five core stakeholder groups with divergent interests:

Regulatory authorities: Mandated to protect human health and environmental safety. They require Good Laboratory Practice (GLP)-compliant safety data on HGT risk, ARGs, and environmental persistence, and bear political accountability for public reaction to GMO approvals.

R&D and industry enterprises: Seek to minimize compliance costs and shorten time-to-market. Divergent classification rules force developers to navigate multiple parallel approval pathways, duplicating testing and wasting capital. For small teams such as iGEM projects, multi-jurisdictional GMM compliance costs can be prohibitive.

Farmers: Prioritize consistent efficacy, predictable costs, and ease of use. Melanin-enhanced Bt offers operational flexibility for large farms and reduced input costs for smallholders, but limited technical knowledge remains an adoption barrier.

Consumers and environmental NGOs: Drive demand for residue-free food, but attitudes towards GMO-derived products vary widely by region. Environmental NGOs often advocate for reduced chemical pesticide use yet oppose GMO technologies on precautionary grounds, creating a paradoxical stance towards genetically enhanced biopesticides.

International trade and standard-setting bodies: Shape global rules for cross-border movement. Alignment with international standards reduces trade friction, while divergent national rules create non-tariff barriers.

Policy Recommendations

To address the regulatory barriers identified and support equitable global adoption of melanin-enhanced Bt, this paper proposes recommendations at three levels.

Global Governance Level

Establish a harmonized international risk assessment framework for GMM biopesticides. Led by the FAO and WHO, develop a unified standard for safety evaluation of genetically modified microbial biopesticides, including agreed data requirements for HGT risk, environmental persistence, and non-target organism toxicity. This would reduce redundant testing across jurisdictions and lower compliance costs.

Create a multilateral data mutual recognition mechanism. Establish a voluntary system among major agricultural economies to accept each other's GLP-compliant safety data for microbial biopesticides, subject to verification of equivalent assessment standards.

Build regulatory capacity in developing economies. Support FAO and regional development bank programs to train biosafety regulators and establish standardized review protocols in low- and middle-income countries, paired with South-South technical exchange programs.

Jurisdiction-Specific Recommendations

United States: Clarify jurisdictional boundaries between EPA and USDA-APHIS for genetically engineered microbial pesticides, and establish a single coordinated review portal to reduce duplicated

submissions. Harmonize state-level registration requirements for low-risk GMM biopesticides.

European Union: Create a distinct regulatory pathway for genetically modified microbial pesticides that separates them from the more restrictive framework for transgenic food crops. Base GMM biopesticide approvals on scientific risk assessment rather than political negotiation, and reduce member state veto authority for products with positive EFSA opinions.

China: Publish detailed, transparent regulatory guidelines for agricultural GMM biopesticides, including clear review criteria, timelines, and decision-making rationales. Expand the capacity and independence of the National Agricultural GMO Safety Committee to reduce political uncertainty.

Brazil: Continue expanding international regulatory alignment partnerships, particularly with Global South nations, to position Brazil as a regional reference point. Strengthen post-market environmental monitoring requirements under the Bioinputs Law to ensure long-term safety tracking.

Industry and Technology Recommendations

Develop a standardized global safety dataset for melanin-enhanced Bt. Generate GLP-compliant data on environmental fate, non-target organism toxicity, and HGT risk that can be submitted across jurisdictions, reducing redundant testing costs.

Invest in smallholder extension and training programs. Partner with local agricultural extension services to provide practical training on proper Bt application timing and methods, addressing the knowledge gap limiting smallholder adoption.

Develop marker-free engineering strains. Eliminate antibiotic resistance marker genes from production strains to address a core regulatory concern and streamline approval across all jurisdictions.

Conclusions

Melanin-enhanced Bt represents a promising technical advance that addresses a key limitation of conventional biopesticides and supports global agricultural sustainability goals. However, its global adoption is impeded not primarily by technical flaws, but by structural regulatory divergence across major economies.

This paper demonstrates that the divergence arises from deeply rooted differences in political philosophy, economic interests, historical public trust, and international trade regimes, rather than mere administrative inefficiency. The U.S. and Brazil prioritize innovation and economic competitiveness with risk-based regulatory systems, while the EU and China maintain more cautious approaches driven by the precautionary principle and social stability concerns respectively. The fragmentation of international trade regimes further amplifies these differences, imposing high dual compliance costs on product developers.

Bridging these regulatory divides requires coordinated action at global, national, and industrial levels. Harmonized assessment standards, data mutual recognition, and targeted capacity building can reduce unnecessary barriers while maintaining appropriate safety oversight. Promoting the global adoption of innovative biopesticides like melanin-enhanced Bt will not only advance agricultural sustainability, but also contribute to more equitable food security outcomes across developing and developed economies alike.

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