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Regulation of Biostimulants under the Fertiliser (Control) Order, 1985: A Critical Analysis of Clause 20C, Schedule VI and the Emerging Compliance Framework in India

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Abstract

The inclusion of biostimulants within the ambit of the Fertiliser (Control) Order, 1985 (FCO) represents one of the most significant regulatory developments in India's agricultural input sector. Unlike conventional fertilisers, biostimulants primarily influence plant physiology rather than serving as direct nutrient source. Their increasing commercial adoption created a regulatory vacuum that demanded scientific validation, quality assurance, and market oversight. The Government's decision to regulate these products under the FCO reflects a transition from an unregulated marketplace to a structured compliance regime. This article analyses the legal evolution of biostimulant regulation, evaluates the emerging compliance architecture, identifies practical challenges faced by stakeholders, and proposes reforms for a more predictable and innovation-friendly regulatory ecosystem.

Keywords: Biostimulants, Fertiliser (Control) Order, 1985, Clause 20C, Schedule VI, agricultural regulation, quality control, compliance, importer, manufacturer.

Introduction

Modern agriculture is increasingly expected to achieve higher productivity while reducing environmental impacts. This expectation has accelerated the development of products that improve nutrient-use efficiency, enhance tolerance to abiotic stress, and promote plant growth without functioning as conventional fertilisers or pesticides. Biostimulants have emerged as an important component of this transition.

For several years, India's biostimulant market expanded in the absence of a dedicated statutory framework. Manufacturers marketed diverse formulations using varying quality standards, while regulators lacked a uniform legal basis for evaluating efficacy and safety. The incorporation of biostimulants into the Fertiliser (Control) Order, 1985 marked a decisive policy shift, signalling the Government's intention to regulate these products through scientific assessment, standardisation, and post-market oversight.

Why Regulation Became Necessary

Before the regulatory framework was introduced, the biostimulant sector experienced rapid commercial growth driven by increasing farmer demand for sustainable crop management solutions. However, this expansion also exposed several systemic concerns.

First, products with widely differing compositions were marketed under similar trade descriptions. Second, claims relating to crop yield, stress tolerance, and nutrient efficiency were often unsupported by uniform scientific evidence. Third, the absence of recognised standards complicated enforcement efforts by regulatory authorities and created uncertainty for genuine manufacturers.

Regulation therefore became necessary not to discourage innovation but to ensure that innovation was supported by credible scientific data and transparent quality standards.

Evolution of the Legal Framework

The legal recognition of biostimulants under the FCO fundamentally altered the regulatory landscape. Through the introduction of Clause 20C and the incorporation of Schedule VI, the Government created a specialised regulatory pathway for these products. The framework introduced a statutory definition of biostimulants, prescribed scientific evaluation requirements, and established product specifications for approved categories. Subsequent amendments have progressively expanded Schedule VI by notifying additional product specifications while refining procedural requirements.

This phased approach reflects a regulatory philosophy that seeks to balance technological innovation with public interest. Instead of permitting unrestricted market entry, the framework gradually incorporates products after technical

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evaluation and specification development.

Scientific Regulation Rather than Commercial Regulation

One of the distinguishing characteristics of the present framework is that regulatory approval is increasingly linked to scientific evidence rather than commercial popularity.

Manufacturers seeking market access are expected to establish through prescribed data, that the proposed product performs its intended biological function without creating unacceptable risks to crops, users, or the environment. Consequently, regulatory scrutiny extends beyond chemical composition and includes efficacy, safety, quality consistency, and manufacturing controls.

This represents an important departure from earlier practices where market availability often preceded comprehensive scientific validation.

Table 1: Regulatory framework across years.

Year	Regulatory Development	Legal Instrument	Regulatory Significance
2021	Formal inclusion of biostimulants under the FCO through insertion of Clause 20C and Schedule VI. A provisional registration mechanism (Form G-3) was introduced to enable existing manufacturers and importers to continue operations while generating scientific data.	S.O. 882(E), dated 23 February 2021	This year marked the shift from transitional regulation to a mature compliance framework. Market access increasingly depended on notified standards under Schedule VI rather than provisional registration, reinforcing scientific validation, quality control
2022	Industry and regulators focused on implementing the newly established regulatory framework. Manufacturers prepared chemistry, bio-efficacy, toxicity, and quality data required for future inclusion of products in Schedule VI.	Administrative implementation of Clause 20C	The year represented a transition from policy announcement to regulatory implementation, with emphasis on scientific documentation, standardisation and stakeholder adaptation.
2023	Expiry of the original provisional registration period was deferred to facilitate completion of scientific studies and regulatory review.	Government extension notifications	The extension reflected a pragmatic regulatory approach, balancing enforcement objectives with the practical realities of generating scientific evidence for a large number of existing products. (Press Information Bureau)
2024	Schedule VI underwent significant expansion through the notification of detailed specifications for recognised categories of biostimulants, including humic substances, seaweed extracts, botanical extracts and related products.	Amendment notifications including S.O. 3922(E)	The framework evolved from procedural regulation to technical regulation by introducing measurable quality specifications, crop recommendations and analytical parameters for approved product categories. (BioAgWorldDigest)
2025	The provisional registration regime was brought to an end. The Government amended Clause 20C to provide a final transition period and clarified that provisional registrations would cease after 16 June 2025. Simultaneously, Schedule VI continued to expand through additional amendment notifications, and laboratory procedures for biostimulant analysis were strengthened.	S.O. 1236(E), dated 17 March 2025, subsequent Schedule VI amendment notifications, and later 2025 amendments	This year marked the shift from transitional regulation to a mature compliance framework. Market access increasingly depended on notified standards under Schedule VI rather than provisional registration, reinforcing scientific validation, quality control and post-market enforcement. (Gazette Tracker)
2026	Continued refinement of Schedule VI through additional product specifications, category expansion, and crop-specific quality parameters for emerging biostimulant technologies.	Amendment Orders issued during 2026	The regulatory framework entered a phase of continuous scientific refinement, demonstrating a move toward a dynamic, evidence-based regulatory model capable of accommodating technological innovation while maintaining quality assurance. (AgroPages News)

Responsibilities of Manufacturers and Importers

The current regulatory model imposes responsibilities that extend throughout the product life cycle. Compliance begins with product development and continues through manufacture or import, storage, labelling, distribution, and post-market accountability.

Manufacturers must ensure that production processes consistently generate products conforming to notified specifications. Importers, although they may not participate in manufacturing, assume regulatory responsibility for products introduced into the Indian market. They must therefore exercise due diligence in selecting overseas suppliers, verifying technical documentation, maintaining traceability, and ensuring conformity with applicable standards before commercial distribution.

In practical terms, compliance has evolved from a documentation exercise into a comprehensive quality management function.

Transition from Provisional Registration to Full Regulatory Oversight

An important feature of India's regulatory evolution was the temporary system of provisional registration. This mechanism enabled existing market participants to continue business operations while generating the scientific evidence necessary for long-term regulatory assessment. After several extensions intended to facilitate industry transition, the Government discontinued the provisional registration regime, requiring continued market participation to be based on compliance with the established framework. (Table 2)

This transition illustrates the principle that temporary regulatory accommodation should ultimately give way to evidence-based approval mechanisms.

Table 2: Transition from provisional to advanced registration.

Milestone	Legal Impact
Introduction of Clause 20C	Created the statutory legal basis for regulating biostimulants under the FCO.
Introduction of Schedule VI	Established technical specifications, product categories, analytical standards and compliance benchmarks.
Provisional Registration (Form G-3)	Enabled an orderly transition for existing manufacturers and importers while scientific evidence was generated.
Progressive expansion of Schedule VI	Allowed new technologies and product categories to enter the market only after scientific evaluation and notification.
Withdrawal of provisional registration	Shifted the regulatory model from temporary accommodation to full statutory compliance based on notified standards.

Regulatory Challenges

Although the present framework has significantly improved regulatory certainty, several practical issues remain.

One challenge concerns the scientific diversity of biostimulants. Products derived from botanical extracts, amino acids, microbial metabolites, and humic substances possess distinct modes of action, making uniform regulatory assessment inherently complex.

Another challenge relates to analytical standardisation. Unlike conventional fertilisers, where nutrient estimation frequently determines compliance, biostimulants often require assessment of biological functionality alongside compositional parameters.

Further, regulatory capacity must continue evolving through improved laboratory infrastructure, harmonised testing methodologies, and specialised technical expertise capable of evaluating increasingly sophisticated formulations.

Strengthening Compliance Culture

Future regulatory success will depend not only on enforcement but also on fostering a culture of voluntary compliance.

Companies should integrate regulatory planning into product development from the earliest stages. Internal quality assurance systems, batch-level traceability, validated manufacturing procedures, periodic product testing, scientific record maintenance, and continuous regulatory monitoring should become routine components of corporate governance rather than reactive compliance measures.

Digital documentation and traceability technologies also present significant opportunities for improving regulatory transparency and facilitating faster inspections.

Future Directions

The regulatory journey of biostimulants in India remains dynamic. As agricultural biotechnology advances, regulators may increasingly adopt risk-based supervision, digital product registration systems, harmonised scientific protocols, and internationally compatible technical standards.

Greater collaboration among research institutions, industry, accredited laboratories, and regulatory authorities could also accelerate the development of evidence-based standards while encouraging responsible innovation.

Ultimately, an effective regulatory framework should protect farmers from substandard products without creating unnecessary barriers for scientifically sound technologies.

Conclusion

The inclusion of biostimulants within the Fertiliser (Control) Order, 1985 represents a significant milestone in the modernisation of India's agricultural regulatory framework. By introducing scientific evaluation, product standardisation, and structured compliance obligations, the legal framework has transformed a previously fragmented market into one governed by measurable regulatory expectations.

The long-term success of this framework, however, will depend upon maintaining an appropriate balance between innovation and regulation. Excessively burdensome procedures may discourage technological advancement, while inadequate oversight could undermine farmer confidence and market integrity.

A transparent, science-driven, and predictable regulatory environment offers the most sustainable path forward. Such a framework not only safeguards product quality but also promotes responsible industrial growth, enhances agricultural productivity, and reinforces confidence in emerging agricultural technologies.

References

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3. Gazette Notifications relating to Clause 20C and Schedule VI.
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