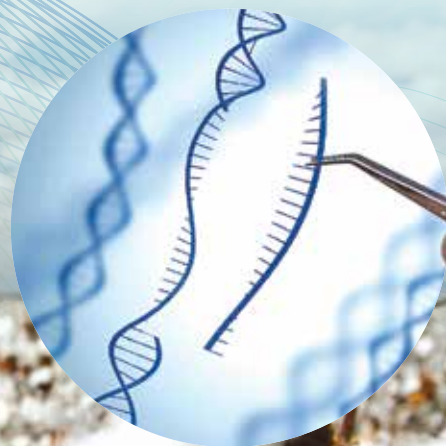




Next-Generation Regulatory Reforms for Genetically Modified and Gene-Edited Crops in India

25 July 2026



Citation : TAAS. 2026. *Policy Brief on Next-Generation Regulatory Reforms for Genetically Modified and Gene-Edited Crops in India*. Trust for Advancement of Agricultural Sciences (TAAS), Avenue II, Indian Agricultural Research Institute, Pusa Campus, New Delhi. 17 p.

ISBN : 978-93-345-3881-6

Published by : **Secretary**
Trust for Advancement of Agricultural Sciences (TAAS)
New Delhi

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Printed : October 2026

Policy Brief

Next-Generation Regulatory Reforms for Genetically Modified and Gene-Edited Crops in India



Preamble

India has established a comprehensive multi-tiered regulatory framework for transgenic crops under the Environment (Protection) Act, 1986 and Rules, 1989. The regulatory ecosystem involves multiple competent authorities, including Institutional Biosafety Committees (IBSCs), the Review Committee on Genetic Manipulation (RCGM) under the Department of Biotechnology (DBT), the Genetic Engineering Appraisal Committee (GEAC) under the Ministry of Environment, Forest and Climate Change (MoEF&CC), the Food Safety and Standards Authority of India (FSSAI), Indian Council of Agricultural Research (ICAR), and other concerned ministries and state governments. Over the past three decades, India has developed robust scientific expertise, institutional capacity and a comprehensive regulatory framework for biosafety assessment, confined field trials, environmental risk assessment food and feed safety

evaluation of biotechnology products as well as seed production and certification system.

The successful commercialization of Bt cotton, currently cultivated across most of India's cotton-growing regions, has clearly demonstrated the transformative potential of agricultural biotechnology. Its adoption has contributed to higher productivity, reduced insecticide use, and enhanced farmer income, highlighting the role of biotechnology in advancing sustainable and economically viable agriculture. At the same time, the regulatory framework governing transgenic crops is in urgent need of critical review and reform in the light of rapid scientific advancements, the emergence of precision breeding technologies such as CRISPR-Cas, evolving global regulatory paradigms and the growing national imperative to develop climate-resilient, sustainable and productive agriculture. Also, India has recently taken important steps towards establishing a differentiated

regulatory framework for gene-edited products, particularly SDN-1 and SDN-2 categories that do not contain foreign DNA. However, greater clarity, harmonization and predictability are still needed across regulatory pathways to effectively accommodate emerging technologies to ensure a smooth and efficient transition from research and development to commercialization. In view of the large amount of scientific data having become available on the safety/risks of genetic modification and related technologies, the current scenario calls for optimization and rationalization of biosafety data requirements, refinement of trial protocols and adoption of updated knowledge-based, risk-proportionate regulatory approaches. Several countries, including the United States, Argentina, Brazil, Japan, Australia and others have already adopted enabling and differentiated regulatory frameworks for specific categories of gene-edited crops to accelerate innovation while maintaining appropriate biosafety safeguards. In this context, India must also harmonize and strengthen its regulatory requirements to ensure enabling and efficient environment for accelerating research in agricultural biotechnology and seed innovation.

Regulatory frameworks for genetically modified (GM) and genome-edited crops face major challenges due to the lack of harmonization, since different countries apply different process-

based and product-based regulatory approaches, leading to regulatory fragmentation and trade uncertainties for biotech product developers. Most of the existing systems had originally been designed for transgenic GMOs, are not suited to emerging genome editing technologies like CRISPR, where small DNA changes may be indistinguishable from natural mutations, creating ambiguity in classification and oversight requirements. This often results in regulatory ambiguity, lengthy approval processes, and increased compliance costs for developers. Additionally, uncertainty in labelling rules, public perception concerns, and precautionary policy approaches contribute to delay in official clearance resulting in inconsistent regulatory update. Together, these bottlenecks raise compliance costs, discourage small biotech research organizations, start-ups and researchers both from private and public-sector, and slow down the development of new crop varieties and traits. For example, the cotton sector, supporting millions of Indian farmers and contributing substantially to the textile economy, is currently facing serious challenges arising from insect resistance, emerging pests, rising production costs and stagnating productivity. underscoring the need for a more efficient, science-based and innovation-friendly regulatory framework. On the contrary available advanced technologies have the

potential to support development of next-generation crop varieties with improved resistance, productivity, sustainability and climate resilience.

The current regulatory and policy environment offers good opportunity to bring in evidence-based reforms aimed at improving operational efficiency, reducing regulatory redundancies, strengthening inter-agency coordination and ensuring transparent, predictable and time-bound approval mechanisms. Such reforms are essential to accelerate innovation, build public confidence, ensure responsible deployment of biotechnology and align India's regulatory framework with the globally accepted scientific standards, emerging technologies and international trade obligations.

Challenges/Constraints

While next-generation plant breeding technologies offer immense potential to transform Indian agriculture, realizing their benefits and putting them in practice requires critical review of a complex landscape of structural, regulatory, and socio-economic challenges/constraints, described below:

Growing Food and Other Agricultural Commodities

Despite significant gains in agricultural production, hunger and malnutrition

remain widespread in the country, reflecting persistent gaps in productivity, access, distribution and equitable food availability. Similarly, in non-food crops like cotton, the recent fall in production has necessitated large imports of raw cotton to meet the soaring demands of the textile industry, threatening industrial stability and farmer livelihoods. This challenge is acutely realized in India's edible oil sector, where the country remains heavily dependent on imports—sourcing 55–60 per cent of its domestic consumption due to stagnant productivity in mustard and soybean. Concurrently, rising pink bollworm and whitefly resistance in older Bt cotton hybrids across major farming belts, like Gujarat and Maharashtra, has stagnated yields, forcing domestic textile mills to rely on foreign raw cotton imports.

Regulatory Modernization and the Cost of Inaction

Existing frameworks, designed primarily for transgenic GMOs, are not well-suited for new genome edited products, leading to ambiguity, overlapping jurisdictions, and lengthy approval processes. These bureaucratic delays and high compliance costs discourage innovation, especially among resource-constrained small research organizations and private sector start-ups. Consequently, sectors such as cotton face severe productivity stagnation and rising input costs, despite

the immediate availability of advanced technologies, proving that regulatory inaction carries immense economic costs. In the Indian context, although the Department of Biotechnology (DBT) exempted Site-Directed Nuclease (SDN-1 and SDN-2) gene-edited plants from strict transgenic regulations under the Environment Protection Act, 2022, the operational hurdle remains high. Public sector institutions such as Indian Council of Agricultural Research (ICAR) and domestic agri-biotech start-ups continue to face prolonged compliance processes and state-level clearance bottlenecks, delaying the development and release of high-yielding, drought-tolerant, and disease-resistant crop strains.

Global Regulatory Fragmentation

Different countries adopt widely divergent regulatory approaches, creating severe international trade uncertainties, market access barriers, and complex compliance challenges for biotech developers operating in global markets. Major trading partners such as the US, Australia, India and Japan regulate SDN-1 and SDN-2 crops as conventional varieties, whereas other global regions maintain strict GMO-equivalent oversight. For India's export-oriented agricultural commodities like *Basmati* rice, tea, and spices, such

global regulatory misalignment creates persistent risks of non-tariff trade barriers and consignment rejections due to differing or undefined international threshold limits for gene-edited traces.

Public Perception and Policy

Uncertainty surrounding mandatory labelling standards, persistent public safety concerns, and over-reliance on precautionary policies create widespread risk aversion among regulators, which further slows down crop approvals, deters private investment, and stifles field-level innovation. The prolonged legal and political impasses surrounding crops like DMH-11 mustard and Bt Brinjal illustrate how Public Interest Litigations (PILs) and activism stall their commercial release in India. Furthermore, prolonging ambiguities in food labelling norms under FSSAI heighten consumer skepticism and disincentivize private sector R&D investments.

Centre-State Regulatory Conflicts in Field-Trial Approvals

Under the Indian Constitution, agriculture is a state subject, whereas environmental safety and biotechnology regulation fall under Central jurisdiction. As a result, Genetic Engineering Appraisal Committee (GEAC) approvals for Biosafety Research Level (BRL) field trials are routinely hindered

because several state governments refuse to issue mandatory No-Objection Certificates (NOCs). This creates localized regulatory blockades, delaying or preventing researchers from executing multi-location field trials across India's diverse agro-climatic zones. A nationally harmonized mechanism is, therefore, needed to ensure that scientifically approved confined trials are not stalled by state-level administrative restrictions.

Outdated Statutory Framework and Institutional Overlap

India's GM governance continues to rely on the "Rules 1989" framed under the Environment (Protection) Act, 1986 — a regulatory framework created decades before modern gene-editing tools like CRISPR/Cas9 existed. The resulting multi-layered regulatory architecture, involving six distinct competent bodies [Institutional Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM), Genetic Engineering Appraisal Committee (GEAC), State Biotechnology Coordination Committee (SBCC), District Level Committee (DLC), and Recombinant DNA Advisory Committee (RDAC)], causes severe jurisdictional overlap. Key reform measures, such as the long-pending Biotechnology Regulatory Authority of India (BRAI)

legislation, remain unfulfilled, leaving developers navigating an inefficient, multi-tiered framework.

Regulatory Over-Enforcement versus Illegal Leakage

While formal regulatory approval channels face extensive multi-year delays, unapproved seed technologies frequently leak directly into the market to meet urgent farmers' demand. The widespread unauthorized cultivation of unapproved herbicide-tolerant Bt (HT-Bt) cotton and unapproved GM soybean across key agricultural states demonstrates that regulatory delays do not halt adoption; instead, they push technology into informal shadow markets. This undermines environmental risk monitoring, deprives farmers of quality-assured seeds, and disincentivizes legitimate intellectual property development.

Opportunities

There are ample opportunities to implement evidence-based reforms. The following steps would lead to harnessing of genetic technologies for agricultural development more effectively, leading to enhanced food and nutrition security, development of agriculture-based industry and welfare of communities dependent on agriculture and related enterprises.

Digitalization of Regulatory Submission and Monitoring

Digitizing the submission and monitoring process through a centralized online portal for applicant tracking, standardizing evaluation protocols and fixed review cycles will minimize administrative delays, improve transparency and accelerate the approval of field trials. In India, expanding the GEAC digital platform into a single-window clearing-house would allow applicants to track filings seamlessly from contained trials to environmental release, eliminating physical paperwork delays between Department of Biotechnology (DBT), Ministry of Environment, Forest and Climate Change (MoEF&CC), and state agencies.

Reduce Redundancies

Duplicative safety trials and overlapping risk assessments across different review stages of regulatory review need to be eliminated, allowing validated scientific evidence to be reused without compromising biosafety standards. Streaming data requirements would allow researchers to reuse validated scientific evidence, reducing costs and delays without compromising safety standards. For Indian researchers engaged in developing SDN-1/SDN-2 gene-edited crops without foreign DNA insertion, avoiding redundant multi-year, multi-location biosafety trials

traditionally mandated for transgenic crops could substantially reduce field-testing time and costs.

Strengthen Inter-Ministerial Coordination

There is need to formalize joint working groups comprising the MoEF&CC, Ministry of Agriculture and Farmers Welfare (MoA&FW), and the DBT. Unified communication channels will resolve jurisdictional overlaps and contradictory decision-making. Synchronizing evaluations between these ministries alongside FSSAI ensures food safety clearances and environmental release authorizations progress in tandem, preventing policy deadlocks.

Establish Time-Bound and Transparent Regulatory Processes

Strict, legally binding timelines for each phase of regulatory evaluation need to be instituted and supported by clear guidance documents for novel technologies. Transparent criteria, defined review periods and public-facing tracking mechanisms would provide greater policy certainty for public research institutions, start-ups, and investors, while reducing delays and administrative uncertainty. Establishing fixed 90-120-day review windows would enable Biotechnology Industry Research Assistance Council (BIRAC)-supported

biotech start-ups, ICAR institutes and private sector to commercialize traits and encourage more investment for developing new products for the benefits of smallholder farmers.

Align with Global Scientific Standards and Trade Obligations

There is an urgent need to adopt internationally recognized, risk-proportionate assessment frameworks — specifically differentiating SDN-1 and SDN-2 gene-edited crops from conventional transgenic GMOs. Harmonizing policies with major trading partners prevents non-tariff trade barriers and enables international research collaborations. Aligning safety evaluation guidelines with *Codex Alimentarius* and Organisation for Economic Co-operation and Development (OECD) frameworks safeguards India's major agricultural exports (such as *Basmati* rice, spices, and tea) from arbitrary trade bans.

Enhanced Food and Nutrition Security

Expedited approval of biofortified, climate-resilient, and yield-enhanced crops can directly address malnutrition, climate volatility, and food supply vulnerabilities across India. Accelerating approval for biofortified crops — including ICAR-developed high-zinc rice, iron-enriched pearl millet (*bajra*),

and low-phytate maize — would facilitate their timely deployment and strengthen national public health and nutrition initiatives such as PM-POSHAN and Mission Poshan 2.0.

Growth of Agriculture-Based Industry

A modernized, and reliable innovation pipeline secures high-quality raw materials (such as domestic cotton, pulses, and oilseeds), while strengthening processing sectors, reducing import dependence, and fostering a robust agri-biotech start-up ecosystem. Deploying gene-edited, high oleic acid mustard and soybean oil varieties could help reduce India's substantial annual edible oil import expenditure while supplying high-quality, pest-free lint to domestic textile hubs in Gujarat, Maharashtra, and Tamil Nadu.

Welfare of Rural and Dependent Communities

Rapid access to advanced seed technologies significantly reduces pest-control input costs, mitigates crop failure risks, and elevates farm income for smallholder farmers. Providing small and marginal farmers (who constitute over 85% of Indian agriculture) with climate-smart seeds — such as flood-tolerant (*Sub1*) rice or drought-resistant wheat — protects yields against

climate anomalies, lowers chemical input expenses, and improves overall livelihood stability.

About the Roundtable Discussion

A multi-stakeholder roundtable discussion was organized by the Trust for Advancement of Agricultural Sciences (TAAS), ICAR and Federation of Seed Industry of India (FSII) at the National Agricultural Science Centre (NASC), Pusa Campus on 25 July 2026, bringing together 73 policymakers, regulators, scientists including international experts, industry, farmers, to deliberate on regulatory reforms, scientific requirements, commercialization pathways, and operational efficiencies, and develop a roadmap for modernizing India's regulatory framework for GM and gene-edited crops with the key objectives to: (i) identify inconsistent data requirements in approval processes; (ii) harmonize national rules with science-based international practices; (iii) evaluate how delayed approvals affect farmers' incomes; and (iv) streamline approval pathways for GMOs/ Living Modified Organisms (LMOs) while upholding strict biosafety standards, to catalyse reforms that will accelerate innovation, ensure biosafety, and strengthen India's position in global agricultural biotechnology.

Recommendations

Institutional and Governance Reforms

1. Regulatory reform functions best as an integrated part of broader innovation ecosystem. Hence, dedicated institutional mechanisms are needed to provide end-to-end support from proof-of-concept validation, regulatory evaluation, to multi-location testing, distinctness, uniformity and stability (DUS) testing, varietal release, seed multiplication, licensing, commercialization and farm level deployment. To achieve this, product development, regulatory approvals and seed-system planning are recommended to proceed concurrently rather than sequentially to significantly shorten the time from laboratory innovation to farmer adoption.
2. To prevent regulatory delays and ensure predictable, time-bound decisions, there is need to fast-track the Biotechnology Regulatory Authority of India (BRAI) Bill in order to establish an independent, science based single-window regulatory Authority free from non-scientific interference.
3. Full statutory authority of GEAC under Rule 1989 needs

to be restored for science-based approvals. This includes appointing a technically qualified Chairperson possessing biotechnology expertise, and broader multi-disciplinary scientific representation to reduce reliance on *ex-officio* members.

4. To eliminate jurisdictional fragmentation and contradictory evaluations that inordinately delay the approvals, there is need to formalize joint working channels with clear roles, timelines, and data-sharing mechanisms among the RCGM, GEAC, and ICAR. There is also a need to create digital infrastructure with accessibility to these regulatory/ facilitating agencies for fast-track processing and real time status of proposals.
5. Since local administrative constraints frequently delay regional field evaluations, the framework is recommended to eliminate mandatory state NOCs for BRL-I and BRL-II trials. After reviewing and granting initial clearance to project proposals involving GMOs to IBSC, delegate approval for approval for confined trials to the RCGM, harmonise national field-testing protocols, and establish adequately funded state-exempt confined testing facilities (CTFs) across all 15 agroclimatic

zones. DBT and ICAR to coordinate jointly for evaluation at designated sites. This approach will reduce administrative delays, ensure uniformity in field testing, and facilitate timely evaluation of biotechnology innovations.

6. There is need to establish legally binding, predictable timelines for regulatory reviews. A formal pre-consultation mechanism between developers and regulators needs to be institutionalised to define trait-specific and risk-proportionate biosafety evaluation studies. Early engagement serves to identify and resolve potential Freedom to Operate (FTO), intellectual property (IP), biosafety, and regulatory issues during product development, rather than at the commercialization stage, thereby, reducing uncertainty, avoiding delays, and facilitating timely market entry.

Biosafety Regulation: Risk Assessment and Stacked Events

7. Recognizing that gene-edited crops free from exogenous or foreign DNA do not pose the conventional risk associated with GMOs, the regulatory agencies need to consider exempting all gene edited products which do not have any

foreign DNA, alongside to the currently exempted SDN-1 and SDN-2 crops from lengthy GMO biosafety protocols. Similarly, the cis-genic crop varieties developed using SDN-3 needs to be treated at par with SDN-1 and SDN-2 products, exempting from lengthy GMO biosafety protocols as they contain full length genes including promoter, etc. from sexually compatible species with history of safe use.

8. To minimize the substantial economic costs of regulatory inaction, there is need to progressively shift effectively from process-based, ultra-precautionary models to product-specific, science-based risk-benefit frameworks that evaluate safety traits pragmatically. Stacking of already approved multiple GM events in a single variety *via* conventional breeding, needs no further testing and approval from agencies except in cases of suspected antagonistic interaction between stacked proteins. Reducing the period of field testing to two years both for the Notified Field Trials (NFTs) and the ICAR-led AICRP on GM crops is necessary to avoid duplication and inordinate delays in approvals.
9. To minimize unnecessary administrative burdens and duplication, stakeholders need to be encouraged to establish a centralized digitized tracking portal, extend the validity of approvals, and eliminate redundant multi-year testing by recognizing verified baseline biosafety data. Also, India needs to consider adopting Data Transportability (DT) principles, allowing the use of existing biosafety risk assessment data and confined field trials data to be utilized across the countries, thereby, shortening approval timelines and reducing costs.
10. Clear, standard operating protocols (SOPs) are essential for step-by-step guidance for the preparation and review of Risk Assessment and Risk Management (RARM) documents, incorporating uniform safety thresholds, and data requirements. Regulatory Authorities need to streamline the submission process by seamlessly integrating RARM documentation directly into the primary biosafety dossier requirements, eliminating duplicate filing, resulting into accelerated regulatory reviews, and meeting defined approval timelines.
11. A predictable framework needs to be developed for event-based approval mechanism (EBAM) to facilitate rapid approval and

commercialization of hybrids and varieties derived from previously approved events, enabling quick state-level registration, eliminating redundant regulatory requirements, and ensuring timely access to advanced seed technologies for farmers.

12. The 2025 stacked-event guidelines are suggested to be revised in line with international “high covers low” principles to prevent redundant testing and unnecessary expenditure. Once individual events or stacked lines have undergone the required safety assessment and received approval, the safety assessment of the same individual components is not required to be repeated for subsequent stacks unless there is a new or scientifically substantial risk warranting additional evaluation.
13. To enhance national food security and reduce import dependence, policymakers need to consider resolving pending legal uncertainties, establish a clear and predictable national policy on GM crops, and fast-track evaluation and approval of proven technologies with established safe-use-history such as HT-Bt cotton and GM maize, oilseed and pulse crops, such as soybean and mustard.

Global Alignment, Trade and Intellectual Property (IP)

14. To prevent non-tariff barriers and secure global market access for Indian agricultural exports, national biosafety, food, and feed safety regulations need to be aligned with international standards such as *Codex Alimentarius* and OECD guidelines. Such harmonization will promote regulatory predictability, facilitate trade, and enhance the global competitiveness of Indian agricultural products.
15. Intellectual property (IP) and FTO issues are best addressed at the inception of product development rather than at the commercialization stage. A national facilitation mechanism is recommended to provide patent landscaping, FTO assessments, licensing support and standardized technology-transfer frameworks, thereby, enabling wider deployment of public-sector innovations and reducing bottlenecks to accelerate commercialization.
16. Seed price regulation mechanism needs to be designed to strike a balance between seed affordability for farmers and fair returns on private sector investment, thereby, encouraging and sustaining the investment in plant breeding,

biotechnology and innovation. This requires a review of the Cotton Seed Price Control Order (CSPCO) 2015, along with establishing a clear and predictable framework for IP and trait protection. Also, there is an urgent need to reconsider compulsory licensing provisions to ensure that they are invoked only under clearly defined circumstances, while preserving farmers' access to improved technologies and maintaining incentives for continued private-sector innovation.

Catalysing Innovation, Investment and Public- Private Partnerships

17. Addressing the large economic drain from import of edible oils requires accelerating the commercial deployment of proven GM and gene-edited crops — particularly the adoption of GM Mustard and pest-resistant pulses and oilseed varieties including HT soybean — to enhance domestic production and productivity, reduce import dependence, and strengthen achieving national self-reliance. A science-based, predictable and time-bound regulatory framework is essential to enable the timely evaluation and commercialization of safe, and proven technologies.
18. There is need to establish streamlined, science-based regulatory pathways to accelerate the development and deployment of climate-resilient traits — including drought and heat tolerance, nutrient and water-use efficiency, and salinity tolerance — in major staples such as rice, wheat, millets, and other dryland crops, strengthening productivity, resilience, and food security under changing climatic conditions.
19. To retain young scientific talent and stimulate cutting-edge domestic innovation, there is an urgent need that government grant “special status” to agri-biotech start-ups, strengthen dedicated funding mechanisms such as the AgriSure Fund, and provide timely, flexible and outcome-oriented research grants. Also, there is a need to establish a stable, predictable and innovation-friendly policy and regulatory environment that encourages both public and private sector investment in agricultural biotechnology.
20. To ensure that advanced biotech seeds reach small and marginal farmers efficiently and affordably, public-sector trait discovery needs to be integrated with private sector's seed development and distribution networks through formalized

Public-Private Partnership (PPP) and licensing mechanisms. Such partnerships aim to leverage the complementary strengths of ICAR's research infrastructure and scientific expertise with private sector's efficient multiplication, commercialization and distribution networks, accelerating the translation of publicly developed technologies into affordable farmer-ready products.

21. In order to eliminate state-level administrative bottlenecks that delay commercial deployment, uniform state-level guidelines for testing, registering, and commercializing the high-performing public and private sector hybrids containing duly cleared biotech events are suggested to be issued under Seeds Act provisions.

Socio-economic Impact and Capacity Building

22. A comprehensive White Paper outlining the biosafety, economic benefits, and cost-of-delay of agricultural biotechnology needs to be developed urgently and submitted to the government. This will build strong political support by highlighting global evidence of over US\$380 billion in farm-income gains and demonstrating the economic impact of delayed adoption.
23. To systematically capture real-world economic and social contributions and track changing public perceptions, there is need to conduct structured *ex-ante* and post-release socio-economic assessments across the value chain. Such evidence-based assessments will support informed policymaking, demonstrate measurable benefits to farmers and consumers, identify emerging concerns and strengthen confidence among policy makers, stakeholders and the public in biotechnology-derived products.
24. For strengthening regulatory enforcement and ensuring reliable GM testing of bulk import and export consignments, GM detection laboratories need to be upgraded with advanced infrastructure, modern analytical technologies and trained technical manpower complemented by continuous biosafety training and capacity building for regulatory authorities.
25. To counter misinformation and build sustained public trust among consumers, farmers, and the media, ICAR in collaboration with think tanks like NAAS and TAAS, etc., need to jointly lead coordinated, nationwide public awareness campaigns. These campaigns will translate complex

biosafety and scientific evidence into clear, accessible, peer-reviewed information for consumers, farmers and media, while proactively addressing misinformation and build confidence in GM and gene-edited foods.

26. The ICAR needs to establish comprehensive, continuous capacity-building programmes and progressively upgrade laboratory infrastructure of ICAR institutions including ICAR-

National Institute of Biotechnology (NIPB), ICAR-Indian Institute of Agricultural Biotechnology (IIAB), etc., and technical capabilities across its institutions to meet emerging biotechnology research and development needs as per requirement. Priority needs to be given to skilled human-resource development, biosafety assessment, product development, and rapid translation of innovations into farmer-ready technologies.



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