Roundtable Discussion on

Reforms in Regulations and Approval of Genetically Modified and Gene Edited Crop Plants

PROCEEDINGS AND RECOMMENDATIONS

25 July 2026

NASC Complex, Pusa Campus
New Delhi, India



Organizers

Trust for Advancement of Agricultural Sciences (TAAS)
Indian Council of Agricultural Research (ICAR)
Federation of Seed Industry of India (FSII)

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Progress Through Science



Trust for Advancement of Agricultural Sciences (TAAS)

GOAL

Harnessing the potential of agricultural sciences for the welfare of people of India

MISSION

Promoting growth and advancement of agriculture through science based policy advocacy, public awareness and effective research and development partnerships

OBJECTIVES

- To act as a Think Tank to deliberate on key issues relating to agricultural research and innovation for development (ARI4D) and to influence policy decisions.
- To organize workshops, conferences, brainstorming sessions, seminars, policy dialogues and special lectures on emerging issues and new developments in agricultural sciences.
- To disseminate knowledge among stakeholders through publication of proceedings, strategy papers, policy briefs and success stories.
- To confer awards on the scientists and farmers of Indian and foreign origin for their outstanding contributions.
- To facilitate scientific interaction and partnerships of non-resident Indian agricultural scientists with Indian scientists.

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Contents

Foreword	...	v
Abbreviations and Acronyms	...	vii
Roundtable Discussion on Reforms in Regulations and Approval of Genetically Modified and Gene Edited Crop Plants	...	1
Background	...	1
About the Roundtable Discussion	...	2
Objectives	...	3
Expected Outcomes	...	3
Opening Session	...	3
Setting the Context	...	4
Keynote Lectures	...	4
General Discussion and Remarks by the Co-Chairs	...	6
General Discussion	...	8
Plenary Session	...	8
Recommendations	...	9
Institutional and Governance Reforms	...	9
Biosafety Regulation: Risk Assessment and Stacked Events	...	10
Global Alignment, Trade and Intellectual Property	...	11
Catalysing Innovation, Investment and Public-Private Partnerships	...	12
Socioeconomic Impact and Capacity Building	...	13
Annexure I : Program	...	15
Annexure II : List of Participants	...	18
Photo Gallery	...	23
Recent TAAS Publications	...	25


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Progress Through Science

Foreword

Indian agriculture stands at a critical juncture. While our public research institutions and private sector innovators have made significant strides in genetic research, precision breeding, and molecular biology, the real-world deployment of these breakthroughs remains severely constrained. The rapid intensification of climate vulnerabilities, shifting pest dynamics, declining natural resources, and persistent reliance on agricultural imports underscore an urgent reality: traditional breeding alone can no longer keep pace with our national imperatives for food, nutritional, and environmental security.

Advanced agricultural biotechnology—both genetically modified (GM) crops and targeted genome-edited (GE) innovations such as CRISPR-Cas offers proven, science-evidenced pathways to build climate resilience, enhance farm productivity, and ensure sustainable livelihoods for millions of smallholder farmers. However, as detailed in this proceedings document, translating laboratory achievements into farm-level impact requires a modern, predictable, transparent, and strictly evidence-based regulatory architecture.

To address these systemic bottlenecks, the Trust for Advancement of Agricultural Sciences (TAAS), in collaboration with the Indian Council of Agricultural Research (ICAR), and the Federation of Seed Industry of India (FSII), convened a high-level outcome-oriented Roundtable on July 25, 2026, at New Delhi. Bringing together over 73 policy leaders, eminent scientists, regulatory authorities, industry representatives, and international economists, the experts critically evaluated India's multi-tiered regulatory framework against current scientific knowledge and global best practices.

This document encapsulates the comprehensive proceedings, detailed expert contributions, and actionable recommendations emanating from the roundtable. It forms the basis of an actionable Policy White Paper designed to provide top government leadership and regulatory agencies with a concrete roadmap for structural reform.

I extend my sincere gratitude to ICAR and FSII, for their partnership, to all the distinguished keynote speakers, panelists, and delegates for their invaluable insights, and to the organizing team for compiling these proceedings. It is my firm belief that implementing these evidence-based reforms will catalyze agricultural R&D, empower smallholders, and position India as a global leader in responsible, sustainable agricultural biotechnology as we march toward Viksit Bharat@2047.



RS Paroda
(*Padma Bhushan Awardee*)
Chairman, Trust for Advancement of Agricultural Sciences (TAAS), and
Former Secretary, DARE & DG, ICAR, New Delhi

Abbreviations and Acronyms

AICRP	All India Coordinated Research Project
APAC	Asia-Pacific Accreditation Cooperation
BCIL	Biotech Consortium India Limited
BRAI	Biotechnology Regulatory Authority of India
BRL	Biosafety Research Level
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CSPCO	Cotton Seed Price Control Order
CTFs	Confined Testing Facilities
DBT	Department of Biotechnology
DT	Data Transportability
DUS	Distinctness Uniformity and Stability
EBAM	Event-based Approval Mechanism
FDI	Foreign Direct Investment
FSSAI	Food Safety and Standards Authority of India
FTO	Freedom to Operate
GE	Gene-Edited
GEAC	Genetic Engineering Appraisal Committee
GM	Genetically Modified
GMO	Genetically Modified Organism
HT	Herbicide Tolerant
IARI	Indian Agricultural Research Institute
IBSC	Institutional Biosafety Committee
ICAR	Indian Council of Agricultural Research
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
IIAB	ICAR-Indian Institute of Agricultural Biotechnology

IIRR	Indian Institute of Rice Research
IP	Intellectual Property
ISAAA	International Service for the Acquisition of Agri-biotech Applications
LMO	Living Modified Organism
MLTs	Multi-locational Trials
MoEFCC	Ministry of Environment, Forest and Climate Change
NAAS	National Academy for Agricultural Sciences
NABI	National Agri-food and Biomanufacturing Institute
NAARM	National Academy of Agricultural Research Management
NBPGR	National Bureau of Plant Genetic Resources
NFTs	Notified Field Trials
NGT	New Genomic Technique
NIPB	National Institute of Biotechnology
NOC	No Objection Certificate
OECD	Organisation for Economic Co-operation and Development
PPP	Public-Private Partnership
R&D	Research and Development
RARM	Risk Assessment and Risk Management
RCGM	Review Committee on Genetic Manipulation
SABC	South Asia Biotechnology Centre
SDN	Site-directed Nuclease
SOPs	Standard Operating Protocols
TAAS	Trust for Advancement of Agricultural Sciences

Roundtable Discussion on

Reforms in Regulations and Approval of Genetically Modified and Gene Edited Crop Plants

BACKGROUND

India 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 (MoEFCC), 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 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 a majority of India's cotton-growing regions, clearly demonstrated the transformative potential of agricultural biotechnology in improving productivity, reducing insecticide use and enhancing farmers' income. At the same time, the regulatory framework governing transgenic crops is in dire need of critical review and reform in response to rapid scientific advancements, the emergence of precision breeding technologies such as CRISPR-Cas system, evolving global regulatory paradigms, and the increasing national requirements for climate-resilient and sustainable and productive agriculture. Also, India recently took 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 of America, 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 developers. Most of the existing regulatory frameworks were designed primarily for transgenic GMOs, are not well aligned with emerging genome editing technologies like CRISPR-Cas, 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 increase compliance costs, discourage small biotech research organizations, start-ups by both private and public-sector biotechnologists, and slow down the development of new crop varieties and traits. For example, the cotton sector, which supports millions of Indian farmers and contributes substantially to the textile economy, is currently facing serious challenges arising from insect resistance, new insects, rising production costs and stagnating productivity. On the contrary, available advanced technologies having the potential to support development of next-generation crop varieties with improved resistance, productivity, sustainability and climate resilience remain sidelined, awaiting timely policy and regulatory approval.

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 also essential to accelerate innovation, strengthen public confidence, promote responsible deployment of biotechnology and align India's regulatory framework with the globally accepted scientific standards, emerging technologies and global trade obligations.

ABOUT THE ROUNDTABLE DISCUSSION

In this context, there is a compelling need for a structured multi-stakeholder dialogue bringing together policymakers, regulators, scientists, public research institutions,

industry representatives, farmer organizations and international experts to deliberate on regulatory reforms, scientific requirements, commercialization pathways and operational efficiencies. Therefore, an outcome-oriented roundtable discussion was organized by TAAS jointly with ICAR, and FSII for suggesting a road map for strengthening and modernizing the regulatory framework on GM and Gene-edited crops based on the current status of science and global best practices with the objective of enhancing regulatory control efficiency, transparency, predictability and robustness for environmental and biosafety clearances.

Objectives

- To identify gaps and inconsistencies in data requirements across GM/GE approval processes
- To explore options for harmonization of national regulatory framework with science-based global practices
- To examine economic implications of delayed or restricted approval of GM/GE technologies on farmers' income
- To develop a road map for efficient approvals of GMOs/LMOs intended for the national needs, ensuring regulatory efficiency and biosafety standards

Expected Outcomes

- Gaps, and inconsistencies in data requirements for existing approval processes identified to be redressed
- Opportunities for harmonizing national regulatory frameworks with global best practices explored and outlined
- Economic implications of delayed or restricted approval of GM/GE technologies assessed
- A clear road map developed for efficient, science-based and time-bound approval of GMOs/LMOs ensuring regulatory efficiency and robust biosafety standards.

OPENING SESSION

Dr Paresh Verma, Director General, Federation of Seed Industry of India (FSII), formally welcomed the distinguished delegates, and stated that the roundtable comes at a critical juncture when Indian agriculture is under intense pressure from extreme weather events, changing pest dynamics, and declining resource availability. Dr Verma highlighted the severe challenges facing Indian agriculture--worsening climate vulnerabilities, unpredictable weather patterns, rising pest dynamics, and declining natural resources. He asserted that genetically modified (GM) and gene-

edited (GE) crops offer proven, scientific solutions to enhance climate resilience, stabilize yields, and improve farmers' profitability. However, the translation of advanced laboratory R&D to field-level adoption is stalled by unpredictable regulatory timelines and institutional friction. Also, he noted that the translation of advanced laboratory innovations into the hands of farmers remains hindered by unpredictable regulatory timelines and policy friction. Dr Verma urged that regulatory processes must be streamlined, transparent, and science-led to encourage both public and private sectors to invest significantly in agricultural R&D, thereby driving the nation's agricultural competitiveness.

Setting the Context

Dr Bhag Mal, Secretary, TAAS, set the context for the roundtable discussion by outlining the current status of agricultural biotechnology globally and nationally. He noted that agricultural biotechnology represents the fastest-adopted technology in modern farming history. Globally, biotech crops cover approximately 190 million hectares (mha) across dozens of countries, benefiting millions of farmers. In India, the introduction of Bt Cotton in 2002 revolutionized the cotton sector, making India a global leader in production. Yet, despite this tremendous success, no biotech food crop has been cleared for commercial cultivation in the country since the moratorium placed on Bt Brinjal in 2010. Dr Bhag Mal detailed the multi-layered regulatory architecture under the Environment (Protection) Act, 1986 and Rules, 1989, which governs GM products. He drew attention to the high compliance costs, administrative duplications, and long delays that are currently associated with approvals. He stressed the importance of gene editing (such as CRISPR-Cas), which can introduce targeted site-directed changes (SDN-1 and SDN-2) without introducing foreign DNA. He called for a transition to a "predictable and enabling" regulatory environment to ensure these transformative technologies are not stalled.

Keynote Lectures

(i) ***Three Decades of Indian Biosafety Experience:*** Dr CD Mayee (President, SABC, New Delhi)

Dr CD Mayee, President, SABC, reviewed India's extensive journey with biosafety and biotechnology over the past thirty years. He detailed how Bt Cotton successfully demonstrated that Indian smallholders enthusiastically adopt scientifically sound, beneficial technologies. The adoption rates of Bt Cotton reached over 95 per cent, drastically reducing insecticide applications and driving socio-economic prosperity in rural areas.

However, Dr Mayee highlighted that subsequent technologies, including GM mustard, have faced persistent administrative hurdles and legal challenges despite passing intensive scientific reviews. This precautionary paralysis leads to a heavy economic cost, with India continuing to spend billions of dollars on import of edible oils annually. To address these persistent bottlenecks, Dr Mayee strongly advocated for the establishment of an independent, statutory regulatory body—the Biotechnology Regulatory Authority of India (BRAI)—to ensure science-led, time-bound, and politically insulated decision-making.

(ii) ***Global Biotech Regulatory Landscapes and Harmonization:*** Dr Rhodora Romero Aldemita (Executive Director, ISAAA, Philippines)

Dr Rhodora Romero Aldemita shared key insights from her paper on global developments in biotechnology regulation. She explained that the world is facing a multi-faceted crisis—combining climate shocks, food insecurity, and supply disruptions—which threatens the UN Sustainable Development Goal 2 (Zero Hunger). To feed an estimated 9.5 billion people by 2050, global food production must increase by 70 per cent. Conventional breeding takes over 10 years, which is too slow to address these rapid challenges.

Dr Aldemita highlighted that gene-edited (GE) crop plants provide a rapid, precise, and cost-effective alternative. Globally, there is a clear trend toward treating SDN-1 and SDN-2 products (which do not contain foreign DNA) as equivalent to conventionally bred crops. This product-based approach is supported in North and South America, Japan, China, Australia, the UK, and recently the EU (under the NGT category). She recommended that: (i) Gene-edited crops indistinguishable from conventional varieties should be exempt from GMO regulations; (ii) Trading nations must collaborate to harmonize regulatory policies to avoid trade disruptions; and (iii) Governments must continuously communicate the environmental and economic benefits of biotechnology to consumers.

(iii) ***Economic and Environmental Impacts of Agricultural Biotechnology:*** Graham Brookes (Agricultural Economist, PG Economics Ltd., UK)

Mr Graham Brookes presented global, data-driven evidence on the economic and environmental benefits of agricultural biotechnology compiled over 25+ years of commercialization. He highlighted that biotech crops generated billions of dollars in additional farm-level economic value globally, mostly benefiting smallholder farmers in developing countries through reduced production costs, improved productivity and stabilizing yields. Environmentally, the technology reduced pesticide use by over 8 per cent and led to major savings in carbon emissions by encouraging no-till farming.

Mr Brookes cautioned that the opportunity cost of delaying biotech and gene-edited crops is enormous. Every year of regulatory delay means millions in foregone farm income, higher pesticide usage, and increased vulnerability of farmers and crops to climate shocks. He concluded that biosafety regulatory frameworks must incorporate realistic, evidence-based economic impact assessments to balance theoretical environmental risks against the proven economic and ecological benefits of technology adoption.

General Discussion and Remarks by the Co-Chairs

Dr Raj Paroda, Founder Chairman, TAAS, asserted that agricultural science and plant breeding must be driven by rigorous evidence, not ideology. He called for an immediate end to the regulatory standstill, urging the government to fast-track scientifically proven, safe technologies currently languishing in the pipeline.

Dr M Ramasami, Founder Chairman, Rasi Seeds, addressed the roundtable from the industry perspective. He stated that while the private seed sector is fully prepared to invest heavily in advanced biotech and CRISPR-based research, it requires a predictable, stable, and encouraging policy environment. He highlighted that ambiguous state-level trial clearances (NOCs) and protracted approval timelines act as major deterrents to long-term private R&D investment.

PANEL DISCUSSION SESSION 1: Building Enabling Environment for Accelerated Testing, Approval and Use of GM/GE Crops

This panel focused on evaluating India's scientific infrastructure, data requirements, and institutional systems to support reforms.

Dr DK Yadava, DDG (Crop Science), ICAR, outlined ICAR's vast research network and capabilities. He emphasized that ICAR is fully prepared to handle biosafety evaluation, and actively standardizing multi-locational field trials to ensure that scientific rigor is maintained without causing administrative delays.

Dr Raman Babu, Global Research Program Director, ICRISAT, focused on dryland crops (millets, sorghum, pulses) that are vital to dryland farming. He urged for simplified regulatory pathways to rapidly bring climate-resilient, nutritionally enhanced gene-edited crops to farmers. He advocated for regional regulatory harmonization in South Asia to facilitate the seamless sharing of elite edited germplasm across borders.

Dr Vibha Ahuja, Former Chief General Manager, Biotech Consortium India Limited-BCIL, highlighted the operational side of regulation. She noted that having guidelines is not enough; we need professional, well-funded secretariats with dedicated staff, clear checklists for applicants, and strict adherence to service-level agreements and time-bound evaluation and clearances.

Dr Raman Meenakshi Sundaram, Director, ICAR-NAARM, highlighted the need to bridge the gap between laboratory breakthroughs and field-level commercialization. He stressed the need for a collaborative Public-Private Partnership (PPP) model to scale up seed production and distribution of newly developed biotech varieties. He suggested that public research institutes should co-develop traits with private players to leverage private delivery networks, ensuring advanced technology reaches farmers faster.

Dr Bharat Char, Chief Science Officer, Mahyco, focused on the private developer's experience, explaining that long, unpredictable timelines for multi-locational trials (MLTs) significantly inflate research costs. He proposed that biosafety data and multi-locational trials (MLTs) conducted in one agro-climatic region should be accepted across similar zones, avoiding redundant and costly trials, thereby, simplifying data requirements.

Dr Gurinder Randhawa, Former Head, Division of Genomic Resources, ICAR-NBPGR, discussed genetic resource management, biosafety testing, and traceability. She proposed that import-export procedures for experimental biotech seeds must be modernized and streamlined to prevent delays in accessing foreign germplasm for domestic research.

General Discussion: During the open floor discussion, participants strongly focused on the requirement of NOCs from individual state governments to conduct scientific field trials. This requirement was identified as the single greatest operational bottleneck, as political variations across states led to an *ad-hoc* and highly inconsistent trial landscape. Delegates urged that a single, central regulatory decision under the MoEFCC should hold authority nationwide for scientific field evaluations. Panelists and delegates agreed that a unified national trial clearance system under a central authority is essential to override regional administrative delays.

PANEL DISCUSSION SESSION 2: Aligning Regulatory Norms Concerning Safety and Risks of GM/GE Technologies

This panel focused on legislative and regulatory frameworks, looking at pathways to remove current bottlenecks and align Indian regulations with global best practices.

Dr Deepak Pental, Former VC, Delhi University, made a passionate critique of India's GM regulatory bottlenecks. Drawing from his first-hand experience in developing GM mustard, he argued that procedural delays driven by non-scientific considerations are severely harming national food security and forcing India to depend heavily on edible oil imports. He urged the government to exhibit decisive political will and implement a streamlined, single-window approval mechanism based strictly on peer-reviewed scientific evidence.

Dr Ashok K Singh, Former Director, ICAR-IARI, highlighted the landmark policy success of India's 2022 guidelines, which exempted SDN-1 and SDN-2 gene-edited crops from stringent GMO regulations. He emphasized that the focus must now shift to the active commercialization of these crops (such as climate-resilient and low-input rice) and ensuring that state-level seed departments are fully aligned with the central guidelines.

Dr Ashwani Pareek, Executive Director, NABI, informed about the research-to-commercialization transition. He proposed establishing public-private incubator funds (such as the Ministry of Agriculture's *AgriSure* fund) to actively support agricultural biotechnology start-ups and public researchers in scaling up genome-edited crop varieties in overcoming regulatory compliance hurdles.

Dr Valasubramanian Ramaiah, APAC Genome Editing Lead, Corteva, discussed the integration of biotechnology regulations with the Seeds Act. He argued that once a crop receives central biosafety clearance, its subsequent licensing, certification, and commercial seed production should be governed by standard seed laws, avoiding repetitive biosafety reviews.

Dr Michael Leader, Regulatory Policy, and Stakeholder Engagement Lead – Asia, Bayer, shared global regulatory insights, noting that excessive and unaligned regulations function as trade barriers. He pointed out that progressive legislative steps—such as the UK's *Precision Breeding Act* and regulatory updates in Australia—serve as excellent models for India to streamline its biotechnology sector and attract foreign direct investment (FDI).

GENERAL DISCUSSION

The general discussion focused on the urgent need to rebuild public and political trust in agricultural biotechnology. Participants agreed that scientific and industry groups must collaborate on proactive, transparent communication, disseminating peer-reviewed data on the safety, yield benefits, and environmental footprints of GM and GE crops to counter misinformation.

PLENARY SESSION

Respective session conveners presented the recommendations of each Panel Discussion session. Consolidated Key Recommendations are presented in a separate section.

Dr DK Yadava, DDG (Crop Science), ICAR, summarized the consensus of the panels, reiterating that ICAR remains committed to advancing cutting-edge, safe, and science-led agricultural innovations. He emphasized that regulatory processes must be robust enough to ensure public trust yet stringently structured, time-bound, and completely

insulated from non-scientific interference, ensuring that Indian farmers are not left behind in the global agricultural biotechnology revolution.

In his concluding remarks, **Dr RS Paroda** expressed his deep appreciation to all keynote speakers, panelists, and delegates for their highly substantive and constructive contributions. He reiterated that science-led agricultural reforms are no longer an option but a vital national necessity to protect millions of smallholder farmers and achieve long-term food security in the face of escalating climate risks. Dr Paroda stressed that TAAS, in partnership with ICAR, FSII, and NAAS, would urgently compile the findings of this roundtable discussion into a comprehensive Policy Paper. This document will be shared directly with the highest levels of government leadership, including the Prime Minister's Office, the Ministry of Agriculture and Farmers Welfare, and the Ministry of Environment, Forest and Climate Change, to serve as a concrete road map for the immediate revitalization and regulatory modernization of India's agricultural biotechnology sector.

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, 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 a need to fast-track the Biotechnology Regulatory Authority of India (BRAI) Bill to establish an independent, science-based single-window regulatory authority free from political and non-scientific interference.
3. Full statutory authority of Genetic Engineering Appraisal Committee (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 Review

Committee on Genetic Manipulation (RCGM), Genetic Engineering Appraisal Committee (GEAC), and ICAR. There is 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 No-Objection Certificates (NOCs) for BRL-I and BRL-II trials. After reviewing and granting initial clearance to project proposals involving GMOs to Institutional Biosafety Committee (IBSC), delegate approval for confined trials to the RCGM, harmonize 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 institutionalized 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 the currently exempted SDN-1 and SDN-2 crop varieties 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 a 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 mechanisms (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 the evaluation and approval of proven technologies with established safe-use-history such as herbicide tolerant HT-Bt cotton and GM maize, oilseed and pulse crops, such as soybean and mustard.

Global Alignment, Trade and Intellectual Property

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

Socioeconomic Impact and Capacity Building

22. A comprehensive White Paper outlining the biosafety, economic benefits, and cost-of-delayed adoption of agricultural biotechnology needs to be developed urgently and submitted to the Government of India. This will build strong political support by highlighting global evidence of over US$ 380 billion in cumulative farm-income gains and demonstrating the economic impact of delayed adoption of technology.
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 programs 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.

Annexure I

Roundtable Discussion on Reforms in Regulation and Approval of Genetically Modified and Gene Edited Crop Plants

25 July 2026

PROGRAM

9:30-10:00	***Registration***	
10:00-11:45	**Opening Session** **Co-Chairs: Raj Paroda**, Chairman, TAAS **M Ramasami**, Founder Chairman, Rasi Seeds (P) Ltd **Convenor: Rajvir Rathi**, Director- Agriculture Affairs & Policy, Bayer Crop Science	
10:00-10:10	Welcome Address	Paresh Verma, DG, FSII
10:10-10:25	Setting the context	Bhag Mal, Secretary, TAAS
10:25-10:40	Need for Reforms in Regulatory Processes	CD Mayee, President, SABC
10:40-10:55	Global Developments in Regulatory Frameworks and Possible Harmonisation	Rhodora Romero-Aldemita, Executive Director, ISAAA Inc
10:55-11:10	Economic Impact of GM/GE Crop Plants	Graham Brookes, Agricultural Economist, PG Economics Ltd, UK
11:10-11:40	General Discussion Co-Chairs' Remarks	All participants Raj Paroda M Ramasami
11:40-12:00	***Tea/Coffee Break***	

12:00-13:30	**Panel Discussion Session - 1: Building Enabling Environment for Accelerated Testing, Approval and Use of GM/GE Crops** **Co-Chairs : ML Jat,** Secretary, DARE & DG, ICAR **Raju Barwale,** Secretary, DBT **Moderator: Ashok K. Singh,** Former Director, ICAR-IARI	
12:00-13:00	Intervention by panelists (5-7 min. each)	**Panellists:** • DK Yadav, DDG (CS), ICAR • Raman Babu, Global Research Program Director, ICRISAT • Vibha Ahuja, Former Chief General Manager, BCIL • Meenakshi Sundaram, Director, ICAR-NAARM • Bharat Char, Chief Science Officer, Mahyco • Gurinder Randhawa, Former Principal Scientist, ICAR-NBPGR
13:00-13:30	General Discussion Co-Chairs' Remarks	All participants ML Jat Raju Barwale
13:30-14:30	***Lunch***	

14:30-16:00	**Panel Discussion Session - 2: Aligning Regulatory Norms Concerning Safety and Risks of GM/GE Technologies** **Co-Chairs : CD Mayee**, President, SABC **Paresh Verma**, DG, FSII **Moderator: Rajvir Rathi**, Director- Agriculture, Bayer	
14:30-15:30	Intervention by panelists (5-7 min each)	**Panellists:** • Deepak Pental, Former VC, DU • Ashok K Singh, Former Director, ICAR-IARI • Ashwani Pareek, Executive Director, NABI • Valasubramanian Ramaiah, APAC Genome Editing Lead, Corteva • Michael Leader, Regulatory Policy & Stakeholder Engagement Lead – Asia, Bayer
15:30-16:00	General Discussion Co-Chairs' Remarks	All participants CD Mayee Paresh Verma
16:00-16:45	**Plenary Session** **Co-Chairs: Raj Paroda**, Chairman, TAAS **NK Singh,** National Professor, ICAR-NIPB IARI **Convenor: RC Bhattacharya**, Director, NIPB	
16:00-16:20	Presentation of recommendations of Panel Discussion Sessions 1 and 2	Convenors of Sessions 1, 2
16:20-16:30 16:30-16-45	General Discussion Co-Chair's Remarks	All participants NK Singh
16:45-17:00	Concluding Remarks and Way Forward	Raj Paroda
17:00-17:10	**Vote of Thanks**	Rajvir Rathi
17:10	***High Tea***	

Annexure II

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