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Gene-Edited Rice and the Risks of Fast-Tracking Regulation

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India's approval of gene-edited rice trials under relaxed GMO rules marks a push for self-reliance with climate-resilient seeds. Yet concerns over patents, costs, transparency, and public trust persist. As global regulations evolve, India's choices may shape its future as a rice exporter.

Rice sustains more than half the world's population and is central to India's food security, rural livelihoods, and its role as the largest global rice exporter. Against this backdrop, India has become the first country to approve field trials of rice varieties developed through gene editing. The decision could influence not only the future of Indian farming but also the way countries govern agricultural biotechnology, as more of them decide how to regulate gene-edited crops.

While proponents argue that gene editing is more precise and less risky than older genetic engineering methods, critics counter that easing oversight could weaken biosafety safeguards.

Between these poles lie answers to a set of questions that will be crucial in the years ahead—how transparent are approval processes, on what terms will farmers actually gain access once technologies exist, and how will licensing agreements be negotiated so that public science delivers public benefit?

India's Approval

In late 2022 and early 2023, two varieties of gene-edited (GE) rice, DRR 100 and Pusa DST1, were cleared for field trials with reduced oversight compared to genetically modified organisms (GMOs). Unlike earlier GM crops such as Bt cotton or GM mustard, these varieties were developed using CRISPR-Cas-based gene editing, which makes targeted changes within a plant's genome without genes from other species.

Under India's updated biosafety framework, edits of this kind, classified as SDN-1 and SDN-2 techniques, are exempt from the multi-tiered review process required for GMOs. Instead, they are cleared by the institutional biosafety committee (IBSC) of the developing institution, following the standard operating procedures newly notified by the department of biotechnology.

This shift is significant. For the first time, rice varieties with genetically altered traits are moving toward farmers' fields without passing through the same layers of centralised scrutiny that shaped India's earlier debates over GM crops. The question is not only whether gene-edited rice performs in the field, but whether a lighter regulatory route can carry the burden of public trust.

Benefits on Offer

In July 2025, I conducted an exclusive interview with Prof. K.C. Bansal, a leading plant biotechnologist. He is the former Director of the Indian Council of Agricultural Research (ICAR)–National Bureau of Plant Genetic Resources (NBPGR), New Delhi, and played a key role in developing the standard operating procedures. In our conversation, he underscored the transformative potential of these varieties. "They are not only higher yielding but also climate-resilient," he explained.

> Equally important, both DRR 100 and Pusa DST1 are varieties, not hybrids, meaning that farmers will be able to save and reuse their seeds.

The two rice lines, DRR 100 (developed from Samba Mahsuri) and Pusa DST1 (from MTU 1010), bring together the desirable traits of higher yields with tolerance to salinity and alkalinity, shorter crop duration, and reduced fertiliser use. For a crop grown across diverse ecologies, such improvements could make a tangible difference.

Shorter-duration rice varieties like DRR 100 are also thought to lower greenhouse gas emissions by reducing the time fields remain flooded. "We are aiming for climate-smart agriculture that does not depend on excessive agrochemical inputs," Prof. Bansal said, stressing that these varieties have been developed in the public sector rather than by multinational corporations.

Equally important, both DRR 100 and Pusa DST1 are varieties, not hybrids, meaning that farmers will be able to save and reuse their seeds. In contrast to hybrids, where seed saving leads to yield loss and dependence on fresh market purchases, these varieties could reduce costs while broadening access.

For farmers, the issue is not only scientific but also economic. Yields of existing varieties have plateaued in many regions, while input costs rise. Improved seeds have thus become a sought-after intervention, sometimes regardless of regulatory status. The spread of unapproved herbicide-tolerant Bt (HTBt) cotton is a reminder—once a technology offers a perceived advantage, farmers will adopt it, whether formally approved or not.

In that light, the promise of gene-edited rice lies not only in its traits but in how it is governed. Falling away from earlier waves of Indian biotechnology development, this time over, public-sector development and varietal breeding address two long-standing farmer concerns—perpetual dependence on proprietary hybrids and restrictions on seed saving. Yet access will ultimately hinge on licensing negotiations for the CRISPR platform and on whether regulatory processes can build the trust needed for informed adoption.

Gene Editing in India

India's embrace of gene editing is not limited to rice. Research is now underway in more than 40 crops across 34 ICAR institutes, supported by a surge in government funding. Funding allocations have gone up from Rs. 406.49 lakh (about $0.49 million) in 2020–21 to a projected Rs. 25,035.08 lakh (about $30 million) in 2025–26, an unmistakable signal that genome editing is central to India's agricultural strategy.

> Could modified genes escape into the wild? Would biodiversity be at risk? This shift from worker safety to ecological safety continues to shape debates today.

With a wide scope, gene-editing projects cover cereals, pulses, oilseeds, fruits, and vegetables. A slew of institutions, ranging from the ICAR and Council of Scientific and Industrial Research (CSIR) to department of biotechnology-affiliated labs, and state agricultural universities are involved in these projects. The ambition is not only to produce higher-yielding or climate-resilient crops but also to establish India as a global hub for biotech-driven agriculture.

From Labs to Fields

India's approach to biosafety has evolved over the decades, following global trends. As Dr. Vibha Ahuja, Chief General Manager at Biotech Consortium India Ltd (BCIL), explained to me in an interview, the regulation of biotechnology products began in the 1970s with a focus on laboratory safety and containment when recombinant DNA techniques first appeared, culminating in the 1976 Asilomar Conference of the world's leading molecular biologists.

The Asilomar Conference set voluntary principles for containment in recombinant DNA research, which directly informed the USA's biosafety guidelines set by the National Institutes of Health (NIH). As scientific capacities and risk perceptions evolved, the NIH progressively relaxed these rules, shifting from strict containment toward more flexible, case-by-case regulation.

By the 1980s, as genetic engineering entered food and agriculture, the scope of biosafety widened to the implications of deliberate release into the biosphere, shaped by growing tensions between industry advocates and environmentalists. Could modified genes escape into the wild? Would biodiversity be at risk? This shift from containment to ecological safety continues to shape debates today.

For DRR 100 and Pusa DST1, biosafety assessments followed the latest streamlined pathway, shaped by deliberations at the NAAS Roundtable of Indian biotechnologists. According to the government, the two gene-edited rice varieties were tested across more than 50 locations under the ICAR–All India Coordinated Research Project on Rice (2023–24). Their institutional biosafety committees submitted data to the regulator, the Review Committee on Genetic Manipulation (RCGM), which in May 2023 confirmed that the lines were exempt from the GMO approval process.

But how the regulators reached this decision remains largely hidden from public view. The only official record, the abridged minutes of the RCGM's 258th meeting in May 2023, merely notes that minutes from 17 institutional biosafety committees were considered and "appropriate decisions were taken". The RCGM released no details on the data reviewed, the discussions held, or the rationale for approval.

That absence of transparency matters. Ostensibly, food carries a deeply cultural and sentimental weight to its consumers. Especially so rice, which is a staple for tens of crores of Indians, bound up with identities, traditions and rituals. When regulatory bodies keep decisions opaque, scepticism multiplies, given what is at stake.

Exemption from Review

The approvals of DRR 100 and Pusa DST1 were made possible by a policy change in March 2022, when the ministry of environment, forest and climate change exempted certain gene-edited crops from the lengthy GMO review process. Under the new rules, edits that do not leave behind foreign DNA—classified as SDN-1 and SDN-2 crops—can now move forward with clearance from institutional biosafety committees, only reporting to the national regulator, the RCGM. After this, it would move through the ICAR and the standard seed release system.

> The result is a pathway that promises efficiency—lower costs, quicker trials, and faster delivery of improved varieties to farmers. But it also sharpens expectations.

Integral to shaping this approach was a 2020 Roundtable meeting of the National Academy of Agricultural Sciences (NAAS) on genome-edited organisms. Prof. Bansal and Dr. Ahuja, who were interviewed for this article, were key members of this meeting.

The roundtable described CRISPR-Cas as the most precise plant-breeding tool available, capable of avoiding the random mutations that come with conventional breeding or older genetic engineering methods. In its recommendation, it argued for the presently simplified route of regulation through the developing institute's institutional biosafety committees. It was finally adopted in 2022 by the department of biotechnology in its standard operating procedures and guidelines.

For many scientists, this distinction was a long-awaited breakthrough, as they claimed that the old framework had slowed down even low-risk innovations. By creating a lighter regulatory track, India aligned itself with countries like the US, Japan, and Argentina, which have also adopted faster approval routes.

The result is a pathway that promises efficiency—lower costs, quicker trials, and faster delivery of improved varieties to farmers. But it also sharpens expectations. Unless regulators pair speed with openness, critics' concern that the process bypasses scrutiny may not be entirely unfounded—an impression that, once formed, is difficult to undo.

Why the Exemption?

The rationale for exempting certain gene-edited crops rests on how CRISPR works. To make an edit, scientists temporarily introduce the Cas9 enzyme and its guide RNA, borrowed from a bacterial immune system, into plant cells. Acting like a molecular pair of scissors, they cut the DNA at the targeted site. Once the desired change is made, the inserted DNA is bred out in subsequent generations. The final plant contains only the intended edit, with no trace of foreign genes.

The recommendation for such an exemption was first raised at the 2020 NAAS Roundtable, particularly the idea that the presence of foreign DNA should determine the regulatory category. The department of biotechnology then incorporated these recommendations into its Guidelines for Safety Assessment of Genome Edited Plants, 2022 and the SOPs for Regulatory Review of SDN-1 & SDN-2 Genome Edited Plants, 2022.

> Supporters also point to precedent. In 2006, India relaxed rules for certain recombinant pharmaceuticals, arguing that products without environmental release risks should not be burdened with GMO oversight.

The guidelines noted that SDN-1 and SDN-2 edits result in genetic changes similar to those from naturally occurring mutations or conventional mutation breeding, and thus merit equal regulatory treatment. Hence, the department exempted them from the GMO-specific risk assessment process. At the same time, SDN-3 plants, where foreign genes remain in the final product, are regulated as GMOs under the 1989 Rules (Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells, 1989).

According to the standard operating procedures, genome-edited plants remain under institutional biosafety committee oversight (with reports sent to the RCGM) until they are confirmed free of exogenous DNA. Once done, the 1989 Rules no longer apply; the institutional biosafety committee needs only to submit the meeting minutes documenting the decision.

There is also a technical dimension. As Dr. Ahuja told me, there is currently no widely accepted method to test with certainty whether a genome-edited plant carries remnants of foreign DNA. Once the temporary constructs are gone, detection is practically impossible. This scientific reality reinforced the case for a separate regulatory track.

Supporters also point to precedent. In 2006, India relaxed rules for certain recombinant pharmaceuticals, arguing that products without environmental release risks should not be burdened with GMO oversight. Supporters argue that SDN-1 and SDN-2 crops should receive similar treatment, since current methods cannot reliably distinguish them from traditional varieties and there is no evidence that they pose environmental risks.

This very indistinguishability could become tricky. If gene-edited crops cannot be reliably detected, how does one label them reliably, give consumers an informed choice, or reassure global trading partners who might not want gene-edited rice in their food systems?

Concerns and Contestations

Clearly, not everyone is convinced that India should be fast-tracking gene-edited crops. A petition by the Coalition for GM-Free India, signed by over 700 individuals working with agriculture, health, and biodiversity, brought some of these issues to the fore. They warned that deployment has outpaced long-term safety research. They also noted that even without foreign DNA, gene editing still alters genes and could cause unintended mutations in ways not yet fully understood globally.

Aruna Rodrigues, a long-time petitioner in India's GMO and biosafety cases before the Supreme Court, frames the issue as one of governance. In a contempt petition filed in July 2025, she alleged a strong risk of regulatory capture, arguing that India's top bodies, including the Genetic Engineering Appraisal Committee (GEAC) and ICAR, maintain close ties with multinational biotech firms such as Bayer-Monsanto and Syngenta.

In a letter to the agriculture minister the previous month, she also criticised the exemption of SDN-1 and SDN-2 rice varieties from multi-tiered biosafety review, calling it a bypass of democratic oversight. For her, the risks are particularly acute given rice's dual role as a global staple and a crop with its centre of origin in India. With over 80,000 rice accessions conserved in national collections, she warns that irreversible gene flow would be an unacceptable gamble.

> Supporters also counter the charge of poor public consultation, pointing to a 2020 NAAS roundtable that brought together academy fellows, industry representatives, progressive farmers, and scientists to discuss genome editing.

The government, however, told Parliament that these varieties are publicly bred from local parent lines and will be distributed via state institutions, posing no threat to seed sovereignty. Supporters also counter the charge of poor public consultation, pointing to a 2020 NAAS roundtable that brought together academy fellows, industry representatives, progressive farmers, and scientists to discuss genome editing, and to which the public comment was invited on department of biotechnology's draft guidelines.

For scientists like Dr. Ahuja, the problem is not the pace of approvals but the persistence of misinformation. "Many of the 40 crops being gene-edited by ICAR do not even pose environmental concerns," she said in our interview, pointing to self-pollinating or non-food crops such as soybean, banana, and rubber, where there is no risk of unintended gene flow. "Unrelenting and unscientific criticism has made scientists' jobs very difficult in India. We are being left behind!"

What about Trade?

India's decision to exempt SDN-1 and SDN-2 crops from GMO rules places it alongside countries such as the US, UK, Japan, Argentina, and Brazil, all of which permit expedited approvals for gene-edited plants lacking foreign DNA. Several African nations, including Nigeria, Kenya, and Ghana, have also adopted lighter-touch regulations.

While the remaining majority are still pondering the question, a few jurisdictions, however, remain cautiously perched on the dividing wall. The European Union still treats genome-edited organisms as GMOs, following a 2018 Court of Justice ruling, though lawmakers are currently hotly debating whether to loosen restrictions. New Zealand has also long maintained a ban, but is also considering changes through its proposed Gene Technology Bill. In these regions, at least for now, gene-edited crops face the same hurdles as transgenics.

This fragmented map matters for India, the world's largest rice exporter. If buyers adopt different standards, exporters could face delays, higher compliance costs, or even outright barriers. And because gene-edited crops without foreign DNA are "technically impossible" to detect, ensuring segregation and labelling in global supply chains will be an impossible challenge.

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As Prof. Bansal told me, this simply reflects diverging national priorities. "The EU doesn't have the population pressure that India does," he said. "We need to secure food production for our growing masses through science-based, evidence-backed solutions."

How this scenario will play out remains to be seen as more countries sort themselves into either side of the evolving regulatory equation.

Patents and Licensing

Even though public institutions developed India's new rice varieties, the CRISPR-Cas9 system they rely on is patented. ERS Genomics, co-founded by French Nobel laureate Emmanuelle Charpentier, holds exclusive licensing rights in over 80 countries, including India.

For research use, ERS offers "freedom to operate" without legal liability. But once crops move towards commercialisation, licences must be negotiated. Talks are already underway. Scientists remain optimistic that the government will reach favourable terms. Prof. Bansal expressed confidence that the government will safeguard farmers' interests, and as Dr. Ahuja said, "India's pharmaceutical industry is a case in point. Once global patents expire, domestic producers can unlock enormous value."

Still, uncertainty looms. Licensing costs could determine whether these seeds remain affordable for farmers, or whether public institutions risk dependence on multinational patent holders.

There is, however, one mitigating factor. The current approvals are for rice varieties, and not hybrids. Farmers will be able to save and replant their seeds, instead of being locked into annual purchases from seed companies. This provides a buffer against high costs at the farm level, but it also raises the stakes for how licensing costs are managed upstream.

Three scenarios are possible. The government could (i) absorb fees centrally; (ii) pass on costs to farmers through higher seed prices; or (iii) wait for patents to expire. But unlike in pharmaceuticals, compulsory licensing is rare in agriculture, and patent expiry could take over a decade, meaning this is the least likely path in the near term. Which option prevails will decide whether CRISPR rice is remembered as a public good or as another battleground over seed sovereignty.

The Road Ahead

India's embrace of gene editing is more than a scientific milestone. It is a political and economic choice about how food, farming, and innovation will be governed in the decades to come. This decision is crucial as it could inspire other countries to follow suit. On the surface, the new rules promise speed, public-sector leadership, and relief from dependence on multinational GM models. But underneath lie more profound questions about trust, ownership, and accountability.

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The technology may be precise, but its social outcomes are anything but predetermined. Whether gene editing strengthens smallholder agriculture or reinforces new forms of dependence and distrust will depend on how licensing deals are struck, how risks are communicated, and whether citizens feel part of the decision-making process.

As science evolves quickly, governance has to keep pace. Public confidence in agricultural biotechnology is fragile, and past missteps with GM crops have shown how easily distrust can harden into anti-technology sentiment.

Other areas of science policy, like pharmaceuticals and drug approvals, show that transparency can build legitimacy, even among sceptics. Agriculture cannot afford the opposite. A perceived opacity in governance risks eroding the credibility of science itself. This is a credibility science can ill afford to lose at a time when rationality and scientific temper in the country remain far from secure.

The coming years will test whether gene editing can live up to its promise without repeating the polarisation that dogged earlier GM debates.

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