GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

RAJYA SABHA
UNSTARRED QUESTION NO. 3167
ANSWERED ON 19.03.2026

Regulatory framework governing gene-editing technologies

3167. SHRI SATNAM SINGH SANDHU:

Will the Minister of **SCIENCE AND TECHNOLOGY** be pleased to state:

(a) the present status of India's regulatory framework governing gene-editing technologies in healthcare, agriculture and biotechnology;

(b) whether any expert committees or public consultations have been conducted to address ethical, social and equity-related concerns arising from gene-editing research;

(c) the extent of indigenous research and institutional capacity being developed in genomics and biomedical ethics; and

(d) whether Government proposes to position India as a global leader in ethically grounded and socially inclusive gene-editing innovation, particularly for rare diseases?

ANSWER

MINISTER OF STATE (INDEPENDENT CHARGE) FOR THE MINISTRY OF SCIENCE AND TECHNOLOGY & EARTH SCIENCES
(DR. JITENDRA SINGH)

(a) The regulatory frameworks governing genetic engineering including gene-editing technologies in healthcare, agriculture and biotechnology within the country are administered by different authoritiesin a coordinated effort.The frameworks in place include:

The Biosafety regulatory framework established under the Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro-organisms/Genetically Engineered Organisms or Cells, 1989 (the "Rules, 1989"), notified under the Environment (Protection) Act, 1986 (EPA) by Ministry of Environment, Forests and Climate Change (MoEF&CC) is applicable on gene-editing technologies in healthcare, agriculture and biotechnology.

Gene-editing led healthcare technologies are further subject to stringent oversight under theNew Drugs and Clinical Trials (NDCT) Rules, 2019 of the Drugs and Cosmetics Act,

1940. Additionally, they are governed by a framework of ethical guidelines and regulatory standards, primarily ensuring the protection of human research participants through Institutional Ethics Committees (IECs). These committees operate under the ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017) and the New Drugs and Clinical Trials Rules (2019).

Gene-edited plants falling under Site-directed nuclease-1 (SDN-1) and SDN-2 categories, which are free from exogenous DNA, have been exempted from the provisions of Rules 7 to 11 (both included) of Rules 1989, vide Office Memorandum No. 12013/3/2020-CS-III dated 30 March 2022 issued by MoEF&CC, and are required to follow "Guidelines for Safety Assessment of Genome Edited Plants, 2022. Further evaluation of gene-edited plants for commercial release is done as per the Seed Act 1966, involving multilocation trials across the country by a third party, i.e., the All India Coordinated Research Project, for the respective crop, for two years.

(b) Yes Sir, an Apex Committee, constituted by the Department of Biotechnology, Ministry of Science & Technology, Govt. of India, on 16-11-2018, prepared guidelines on Genome Editing Technologies, Applications & Regulations. The draft "Genome edited organisms: Regulatory Framework and Guidelines for Risk Assessment" was published in January 2020 for public consultation, with comments invited by February 8th, 2020.

On 30th March 2022 the Ministry of Environment, Forest and Climate Change, Govt. of India, issued an Office Memorandum on 30th March 2022, exempting SDN-1 and SDN-2 genome edited plants (free of exogenous DNA) from Rules 7-11 (both inclusive) of the Rules 1989 of Environment (Protection) Act, 1986. Pursuant to this, the Department of Biotechnology (DBT), Ministry of Science and Technology (MoST), notified the "Guidelines for the Safety Assessment of Genome Edited Plants, 2022" and the "Standard Operating Procedures (SOPs) for Regulatory Review of Genome Edited Plants under SDN-1 and SDN-2 Categories, 2022", which offer internationally harmonized best practices and foster efficiency in biotechnology regulation.

Ethical aspects in gene-editing research are addressed under the existing national ethical framework, specifically Chapter 10 (Human Genetic Testing and Research) of the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017. These guidelines cover ethical issues related to newer technologies, including gene-editing, emphasizing ethical oversight, stakeholder engagement, and capacity building to ensure safety and responsible research.

Similarly, the National Guidelines for Gene Therapy Product Development and Clinical Trials (2019), released by ICMR, CDSCO & DBT, provide a framework for safe, ethical development and testing of gene therapy products.

(c) & (d) The Government of India, through various ministries and departments, has established a robust biotechnology, genomics, and biomedical ethics research ecosystem,

positioning India among the global leaders in ethically grounded and socially inclusive gene-editing innovation. Research in gene-editing technologies is being undertaken across public research laboratories, universities, and biotechnology institutes spanning areas from crop improvement to biomedical research.

The Department of Biotechnology (DBT) has made significant progress in promoting genomics led genome-editing research and its application in agriculture, focusing on developing improved crop varieties with enhanced productivity and stress resilience. The recent exemption of SDN1/SDN2 genome-editing has paved the way for harnessing this technology for climate resilient crops. In this context, DBT is prioritizing the development and deployment of genome-editing technologies to improve key crops such as rice, maize, mustard, groundnut, pigeonpea, potato, and tomato, focusing on traits like stress resilience, input-use efficiency, nutritional quality, and yield.

The Indian Council of Agricultural Research (ICAR) initiated genome-editing in rice in 2018 and has since developed the world's first genome-edited rice varieties, Pusa DST Rice 1 and DRR Dhan 100 (Kamala). Building on this success, ICAR has invested Rs 500 Crores in genome-editing, with 53 institutes working on crops, insects, microbes, fishes, animals, and diagnostics development. To further enhance capacity, ICAR has trained scientists at international labs abroad, with 18 scientists trained in 2024-25 and 21 selected for 2025-26. Additionally, over 100 scientists have been trained in India at institutes like ICAR-Indian Agricultural Research Institute, ICAR-National Institute for Plant Biotechnology, and ICAR-Central Rice Research Institute.

ICAR-Central Rice Research Institute, Cuttack has developed a compact alternative, TnpB, a transposon-associated nuclease only 408 amino acids long one-third the size of Cas9/Cas12a. TnpB has shown high performance in both monocots (rice) and dicots (Arabidopsis), achieving up to 69% editing efficiency. A patent has been granted for "Systems and Methods for Targeted Genome Editing in Plants", centred on this miniature RNA-guided nuclease TnpB, which is expected to open up new avenues for efficient delivery and precise editing, positioning India at the forefront of next-generation genome engineering.

The Department of Biotechnology is supporting the Indian Tuberculosis Genomics Surveillance Consortium (InTGS) programme, which involves whole genome sequencing of 30,000 *Mycobacterium tuberculosis* isolates to catalogue existing and emerging resistance mutations and study the association of different *Mycobacterium tuberculosis* lineages with treatment outcomes. The programme aims to leverage genomics and artificial intelligence to map drug resistance, enabling rapid identification of drug-resistant strains in patients, and ultimately support evidence-based strategies for more effective tuberculosis control and management.

The Indian Biological Data Centre (IBDC) is India's first national repository for life science data, established at the Regional Centre for Biotechnology (RCB) in Faridabad. Supported by the Department of Biotechnology (DBT), it archives publicly funded biological data

(including genomic data), provides high-performance computing (BRAHM), and offers open-access to data sets adhering to FAIR (Findable, Accessible, Interoperable, Reusable) data principles.

The Department of Biotechnology (DBT) has implemented the Mission Program on Pediatric Rare Genetic Disorders (PRaGeD) in 2022, a PAN-India initiative involving 16 institutions, coordinated by DBT-BRIC-CDFD, Hyderabad. PRaGeD aims to create awareness, achieve genetic diagnosis, discover and characterize new genes/mutations, provide counselling, and develop new gene therapies for pediatric rare genetic disorders in India.

The Department has also supported a first-in-human Phase-I clinical trial for gene therapy of Hemophilia A, which has shown clinically significant outcomes, with stable production of Factor VIII observed, offering potential long-term reduction of bleeding episodes, and paving the way for further human studies. Research grants being considered under the precision biotherapeutic program include developing gene therapies for hematological diseases like Hemophilia-A, gene editing therapy for Thalassaemia, and mRNA-based protein replacement therapy for Hemophilia B. In CAR-T cell therapies, academia projects focus on developing bi-specific CAR for Multiple Myeloma and demonstrating in situ CAR-T cell reprogramming via viral vector delivery in a humanized mouse model.

A public sector undertaking of DBT, Biotechnology Industry Research Assistance Council is actively working on regulatory preparedness and gene-editing innovation for Cell & Gene Therapy (CGT), including rare diseases, through focused initiatives such as webinar series and industry-academia stakeholders meets. Similarly, DBT also organizes fortnightly online interactive sessions to promote biosafety across India's research ecosystem, familiarizing participants with the nation's biosafety regulations and equipping them with practical tools for compliant, sustainable research practices. These initiatives have drawn over 700 attendees, including faculty, students, scientists, industry professionals, and start-up innovators, creating a collaborative network that reinforces adherence to biosafety standards nationwide.

The Indian Council of Medical Research (ICMR) supports research and provides grants for studies on therapeutic approaches for rare diseases, including gene-editing and gene therapy. These initiatives, undertaken at leading biomedical research institutions and medical colleges, aim to build national expertise, infrastructure, and human resource capacity in advanced genomics and translational research, strengthening indigenous capabilities while ensuring compliance with ethical guidelines and regulatory frameworks.

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