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REGULATION OF NOVEL GENETIC ENGINEERING IN CROPS

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ABSTRACT

In view of the novel technological development in the Indian agricultural sector, there is a need for the pragmatic regulation of agricultural biotechnology. Agricultural biotechnology's advancement has sparked a widespread discussion about its potential to revitalise Indian agriculture, but, also its possible hazards on accounts of biosafety, biodiversity, and the environment. In India, for example, there have been numerous discussions around genetically modified crops, particularly, Bt Cotton and Bt Brinjal. Additionally, these case studies have shown that India's current legal and regulatory framework for agricultural biotechnology is inadequate. A Bill - The Biotechnology Regulatory Authority Bill was proposed, but it has been pending in the Parliament since 2013. Nevertheless, the Bill is deficient in a number of areas in its current form. A wide number of concerns regarding agricultural biotechnology have not been adequately addressed by the law, including those related to the environment, intellectual property, ethics, the balance between public and private interests, etc. Several leading research institutes in India have developed new varieties of crops by using latest technologies by genetic engineering. For instance, a recent breakthrough gene editing tool, known as CRISPR, has opened new avenues for crop development. In this technology, the gene that is already present in a plant is edited without bringing in any foreign gene. As the new protein doesn't come from an outside organism, the need for safety tests doesn't arise, unlike in the case of transgenic crops like Bt Cotton. However, due to the lack of guidelines, and due to regulatory issues, these varieties are yet to be tested in the open fields before their release to the farmers. The author aims to offer insight into Genetically Modified Crops and their impact on the environment in the aforementioned context. In the process, the author attempts to illustrate the legal framework in place in India that govern Genetically Modified crops, and its shortcomings. Finally, the author endeavors to put forward suggestions for the government to take a proactive stand to bring about the proposed legislation while incorporating the suggestions to the inherent shortcomings in order to

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effectively utilise, and regulate the novel gene editing technologies for the benefit of Indian farmers.

Key words: Agricultural biotechnology, CRISPR, Gene editing Technologies, Genetic Engineering, The Biotechnology Regulatory Authority Bill

INTRODUCTION

Genetically modified (GM) or genetically engineered crops are plants **used in agriculture, in which the DNA has been modified for a specific purpose by using genetic engineering techniques.**² In most cases of genetic engineering, the aim is to introduce a new trait to the plant which does not occur naturally in the species like resistance to certain pests (insect resistance), diseases, environmental conditions, herbicides (herbicide tolerance), stacked traits, etc.³ However, certain associated risks like that to the human health by the introduction of new food allergens, environment through the flow of genes to non-target species as a result of cross pollination resulting in the creation of super weeds and super pests,⁴ loss to the genetic makeup and diversity in species,⁵ etc are present.

INTERNATIONAL REGIME RELATING TO THE BIOSAFETY IN GM PLANTS

India is a party to the Convention on Biological Diversity (CBD), 1992 and ratified the Cartagena Protocol on Biosafety in 2003 which protects biodiversity from potential risks of GMOs and the products of modern biotechnology.

Advance Informed Agreement⁶ is a significant feature of the Protocol, which enshrines the precautionary principle.⁷ Under the Agreement, the exporting nation is required to notify the importing nation of its intention to export GMOs.⁸ The importing country can base their decision to

² *What is genetic modification (GM) of crops and how is it done?*, THE ROYAL SOCIETY (May, 2016), <https://royalsociety.org/topics-policy/projects/gm-plants/what-is-gm-and-how-is-it-done/> accessed Oct. 5, 2022.

³ David. J. Schiner, *Genetically modified organisms and the Cartagena Protocol* 379 (Fordham Enytl. L.J., 2001).

⁴ David. J. Schiner, *Genetically modified organisms and the Cartagena Protocol* 394 (Fordham Enytl. L.J., 2001).

⁵ A. A. Snow et al., *Genetically Engineered Organisms and the Environment: Current Status and Recommendations, Ecological Applications* 377 (Ecological Society of America, 2005).

⁶ Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Art. 7 – 10, 12, 2000.

⁷ Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Art. 10.6, 2000.

⁸ *Ibid.*

ban an import due to the potential risk it poses to human health and environment, even in the absence of sufficient scientific information about the kinds and extent if risk.⁹ The Protocol, however, does not outline any method of dispute resolution procedure or liability for environmental harm brought on by the GM technologies.

INDIAN BIOSAFETY REGIME FOR REGULATING GM CROPS

In light of the above discussion, it would be appropriate to assess the domestic regulatory system. The first major regulation was the Environment (Protection) Act of 1986 to provide a holistic framework to protect and improve the environment. Under Section 25 of the Act, specific provisions were made in 1989 for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells.¹⁰ They are popularly known as the 'Rules of 1989'.¹¹ They are meant to be the apex provision for regulation of all activities related to genetic engineering. They cover areas of research as well as large scale application of genetically modified organisms and their products. Further, they provide for dispute resolution and penalties in cases of non-compliance.

These Rules are implemented by the Ministry of Environment, Forest, and Climate Change; Department of Biotechnology; and State governments through six competent authorities, namely; rDNA Advisory Committee (RDAC), Institutional Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM), Genetic Engineering Appraisal Committee (GEAC), State Biotechnology Coordination Committee (SBCC), District Level Committee (DLC). The major roles of these authorities are as follows: RDAC has an advisory function; the IBSC, RCGM, and GEAC are responsible for the regulating function. The SBCC and DLC are for monitoring purposes. The interaction mechanism among these provides that all IBSCs are required to review the applications and submit their recommendations and reports to RCGM from time to time. The release of guidelines by Indian regulatory authorities includes in their ambit research and development activities.

⁹ Swati Singh & Upasana Rajaram, *India's Genetic Monsters* (Envtl. L. & Prac. Rev., Working Paper No. 86, 2011).

¹⁰ The Environment Protection Act, 1986, §25, No. 29, Acts of Parliament, 1986 (India).

¹¹ Rules for manufacture, use/import/export & storage of hazardous microorganisms/genetically engineered organisms or cells, 1989, G.S.R. 1037 (E). (India).

Recombinant DNA Safety Guidelines with a major emphasis on research and development activities on GMOs, shipment, and importation for laboratory research etc. came into the existence in the year 1990.¹² As per the Rules, 1989, the Genetic Engineering Approvals Committee (GEAC), a body under the Ministry of Environment and Forests was given the responsibility for approval of genetically engineered products in India.¹³ The GEAC is chaired by the Special Secretary/Additional Secretary of MoEF & CC and co-chaired by a representative from the Department of Biotechnology (DBT).

The guidelines for the safety assessment of foods derived from genetically engineered plants were prepared by the Indian Council of Medical Research (ICMR) and adopted by the RCGM and GEAC in the year 2008.¹⁴ Similarly, MoEFCC along with the DBT has adopted a series of documents to strengthen the environmental risk assessment of GM plants in India. These include: Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016; Environmental Risk Assessment of Genetically Engineered Plants: A Guide for Stakeholders and Risk Analysis Framework, 2016; Guidelines; User's Guide and Risk Analysis Framework In: Environmental Risk Assessment of GE Plants 2016.¹⁵

In 2014, the DBT constituted a dedicated Task Force on "Genome Engineering Technologies and their Applications" with a vision to foster innovation and promote development of Genome-wide Analysis and Engineering Technologies to make them accessible and affordable for wider use in life sciences.¹⁶

The Biotechnology Regulatory Authority of India (BRAI) Bill, 2013, was introduced with an objective to promote the safe use of modern biotechnology. BRAI was meant to regulate the research, transport, import, containment, environmental release, manufacture, and use of biotechnology products.¹⁷ The National Biotechnology Regulatory Authority (NBRA) was envisioned by the Bill,

¹² Recombinant DNA Safety Guidelines, 1990.

¹³ *Supra* note 10.

¹⁴ Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008.

¹⁵ Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016; Environmental Risk Assessment of Genetically Engineered Plants: A Guide for Stakeholders and Risk Analysis Framework, 2016; Guidelines, User's Guide and Risk Analysis Framework In: Environmental Risk Assessment of GE Plants 2016.

¹⁶ Vibha Ahuja, *Regulation of emerging gene technologies in India* (BMC Proceedings, Working paper No. 12 (Suppl 8): 14, 2018).

¹⁷ The Biotechnology Regulatory Authority of India (BRAI) Bill, 2013, PRS LEGISLATIVE RESEARCH, <https://prsindia.org/billtrack/the-biotechnology-regulatory-authority-of-india-bill-2013>, accessed 3 October 2022.

and it was proposed to establish the NBRA under the DBT, therefore eliminating all other areas of interest that have an impact on India's biotechnology sector; notably, the social, agricultural, and economic realms.¹⁸ However, this Bill lapsed and further action on the same is awaited, affecting the pace of research work in the field of genetic engineering of crop plants in the country.

DRAWBACKS OF THE EXISTING FRAMEWORK

There is no apparent hierarchy or distinction among the many bodies in the biosafety framework. Despite provisions for authorities such as the SBCC and the DLC at the de-centralized level, these regulatory bodies have not been set up in most of the states and districts of the country.¹⁹ Similar confusion exists with legislations also; at least five existing legislations in force in India have a potential impact on the regulation of GM products in the country.²⁰ It is paramount for the biosafety regulatory bodies to recognize the shortcomings and come out with sensible solutions.

The regulatory bodies, primarily the RCGM and the GEAC, are constituted mostly by members of public sector institutions and government bureaucrats along with representation from the scientific disciplines²¹ excluding public participation, which is in severe violation of the CBD²² as well as Cartagena.²³ Our regulatory mechanism does not take into consideration the value of the biodiversity to the indigenous and local communities, thus choosing to ignore to assess the socio-economic impact of GMOs.²⁴

A poor liability regime is another concern: firstly, non-compliance with the legal requirements, and secondly, damage caused to the environment as well as socio-economic and other forms of damages. The domestic regime completely fails to address the latter.²⁵ There is no provision for any sort of

¹⁸ *Ibid.*

¹⁹ Suman Sahai, *GMO Regulations in India and their Weakness*, GENE CAMPAIGN, genecampaign.org/Publication/Article/gmo-reg-india-weakness-pl=ID1.htm, accessed 3 October 2022.

²⁰ Prevention of Food Adulteration Act, 1954, the Seed Act, 1966, the Biosecurity Regulations, the National Biodiversity Act, 2002 and the Protection of Plant Varieties and Farmers' Rights Act, 2001.

²¹ Aarti Gupta, *Ensuring 'Safe Use' of Biotechnology: Key Challenges* 2763 (Economic and Political Weekly, 2002).

²² Convention on Biological Diversity, Art.14(1), 1992, 1760 UNTS 79.

²³ Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Art. 23, 2000.

²⁴ A. Damodaran, *Re-Engineering Biosafety Regulations In India: Towards a Critique of Policy, Law and Prescriptions* (Environment and Development Journal, 2005).

²⁵ *Supra* note 17.

compensation or confiscation, except under the EPA where there is a provision for fine and imprisonment.²⁶ In the existing mechanism there is no provision for labelling of GM products in order to segregate transgenic crops from the non-transgenic ones.²⁷

The Bill does not address any of the prevailing lacunae in the regulatory mechanism, be it the lack of public participation or the non-recognition of the Precautionary Principle as a legally binding instrument. For instance, the provision which penalizes a person who, without any scientific evidence or scientific record, 'misleads' the public about the safety of the organisms and products with imprisonment and fine.²⁸ It overrides State Authority and gives them only an advisory role when agriculture is in reality a State Subject under the Constitution.²⁹ This discourages state participation and further weakens the monitoring mechanism.

CONCLUSION

Till date, Bt cotton is the only GM crop approved for commercial cultivation in India. Regarding regulation of genome engineering technologies, there is still a debate in the country. Clarity of procedure and lack of unanimous opinion about the safety and precautions to be taken for utilizing the recent genetic technologies is affecting the regulatory mechanism of biotechnology in India.

It is important that we carry out our international commitments, such as implementing the Precautionary Principle, taking socioeconomic considerations into account, encouraging public participation, requiring labelling, and similar concerns. One step in this direction would be a stand-alone Gene Technology Legislation³⁰ inclusive of the above-mentioned features as well as a strong liability clause, and dispute redressal mechanism.

²⁶ The Environment Protection Act, 1986, §15, No. 29, Acts of Parliament, 1986 (India).

²⁷ Alexander G. Haslberger, *Monitoring and Labelling for Genetically Modified Products*, (American Association for the Advancement of Science, Working Paper No. 431, 2000).

²⁸ *Supra* note 9.

²⁹ Mahim Pratap Singh, *Activists Voice Concern over Biotech Regulatory Authority Bill*, THE HINDU (Feb. 18, 2010), <http://beta.thehindu.com/news/national/article108821.ece>.

³⁰ Suman Sahai, *The BT Brinjal Case: Overhauling the Regulatory System must be the First Step*, GENE CAMPAIGN, [http://www.genecampaign.org/Publication/Article/GMtech/the Bt brinjal-caseoverhauling-the-regulatory-system-must-be-the-first-feb10=ID3.html](http://www.genecampaign.org/Publication/Article/GMtech/the+Bt+brinjal-caseoverhauling-the-regulatory-system-must-be-the-first-feb10=ID3.html), accessed 3 October 2022.

Another aspect which requires consideration is the infrastructural setup. The fact that risk assessment tests are carried out in the private laboratories of the biotech companies rather than independent, publicly financed institutions could lead to a conflict of interest.³¹ Further, it may be prudent to incorporate certain assessments, one being a performance assessment and the other a need assessment.³² Considering the early stages of gene technology that India is in, it could be a good idea to set up a performance assessment system after commercial release of GM crops.



³¹ R. Ramachandran, *Global Spread*, FRONTLINE (Mar. 12, 2010), <https://frontline.thehindu.com/cover-story/article30179455.ece>.

³² *Supra* note 27.