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BIO SAFETY GOVERNANCE IN INDIA- Siya Jindal¹**ABSTRACT**

The instant paper is an attempt to understand Biosafety Governance in India in relation to the environment and environmental laws in the country. This research paper introduces to the readers new terms like biosafety, GMO and LMO. It further discusses the importance of biosafety in India. The paper will examine biosafety governance with respect to the Convention on Biological Diversity, the Cartagena Protocol on Biosafety, the Environment Protection Act 1986 and the Biological Diversity Act 2002. The paper also educates the readers about the relevant judgments given by the apex court in relation to biosafety and towards the end gives a critical analysis of the Biosafety Governance in place in India.

KEYWORDS: Biosafety, Genetically Modified Organisms (GMO), Living Modified Organisms (LMO), Biosafety Governance, Biosecurity.

INTRODUCTION

The World Health Organisation after years of study has given its own definition of biosafety that says “biosafety is a strategic and integrated approach to analysing and managing relevant risks to human, animal and plant life and health and associated risks for the environment. It is based on recognition of the critical linkages between sectors and the potential for hazards to move within and between sectors, with system-wide consequences”.²

In simple words Biosafety is a term used to describe efforts to reduce and eliminate the potential risks resulting from biotechnology and its products. where biosafety governance is a term used to refer to all the rules, regulations, policies, procedures and principles made to

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²*Biosafety: crucial in the fight against pandemics*, IBEDROLOA (Last visited 1st June'23, 5:00 pm) available at: <https://www.iberdrola.com/innovation/what-is-biosafety>

protect the environment and humans from the dangers of bioengineering and create a safeguard against them.³

Where, biotechnology is a technique that uses living cells to develop or manipulate products for specific purposes. Biotechnology is thus related to genetic engineering that utilizes biological systems or living organisms to create different products with varied genetic modifications.

There are three important concepts in the field of biosecurity/biosafety⁴:

- **Biological hazard:** it is the potential risk of uncontrolled exposure to biological agents that cause disease and prove to be detrimental to the human and animal population.
- **Biocontainment:** are measures taken to prevent infectious diseases from leaking from research centers or other places where they may be created.
- **Bioprotection:** it is a set of measures taken to reduce the risk of loss, theft, misuse or intentional release of pathogens and toxins, including those governing access to facilities, materials storage and data.

Biosafety governance involves protecting human, animal health and the environment from the possible adverse effects of the products of modern biotechnology with the help of rules and regulations. The Cartagena Protocol on Biosafety includes the mention of such products of biotechnology. They are known as GMOs and LMOs.

GMOs are Genetically modified organisms (GMOs), they can be defined as plants, animals or microorganisms in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination. The technology that is used to create these organisms is also often called “modern biotechnology” or “gene technology”.⁵

³What is Biotechnology ?, BIOTECHNOLOGY INNOVATION ORGANISATION (Last visited 2nd June’23, 2:00 pm) <https://www.bio.org/what-biotechnology>

⁴ *Supra note 1*

⁵Food, genetically modified, WORLD HEALTH ORGANISATION, (Last visited 31st May’23, 12:57 am) available at <https://www.who.int/news-room/questions-andanswers/item/food-genetically-modified>

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LMOs are defined as any living organisms that possesses a novel combination of genetic material obtained through the use of modern biotechnology⁶. LMOs have been defined in the Cartagena Protocol on Biosafety. When talking in respect of the Cartagena Protocol on Biosafety, GMOs and LMOs are used as interchangeable terms in India.

IMPORTANCE OF BIOSAFETY IN INDIA

- ✧ With the advancement of genetic engineering or modern biotechnology, biosafety measures have become very important to protect the people and the environment from the adverse effects of GMOs and LMOs. They help in keeping a check on these potentially harmful biological agents.
- ✧ Growth of modern technology is inevitable and also very beneficial as it aims at improving the quality of life of people but it can prove to be dangerous if not used wisely. The danger that it poses can go very quickly out of control if not paid proper attention to.
- ✧ Biosafety is an important mechanism of ensuring safe utilisation of technology and available resources. Bioterrorism, which is the deliberate release of viruses, bacteria, toxins or other harmful agents to cause illness or death in people, animals or plants⁷ is an emerging issue. Biosafety measures prove to be very important and helpful in such situations.
- ✧ With the introduction of modern technology and the emerging trend of fast living, the sustainable development goals are overlooked more than often. Biosafety to some extent ensures that the environment is preserved keeping the future generations in mind by preventing the environment from getting damaged or destroyed.
- ✧ Biologically active agents can cause disease in other living organisms or cause significant impact to the environment or community. Biosafety helps in protecting the environment and the community from this risk.
- ✧ The advent of Covid 19, a deadly virus which infected the world and alarmed all the nations with a horrific medical emergency causing thousands of people to die everyday

⁶ *Cartagena Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY, (Last visited 6th January'23, 8:00pm), https://bch.cbd.int/protocol/cpb_faq.shtml#:~:text=In%20everyday%20usage%20LMOs%20are,resistance%20to%20pests%20or%20diseases.

⁷ *Bioterrorism*, INTERPOL, available at: <https://www.interpol.int/en/Crimes/Terrorism/Bioterrorism> (Last visited 5th May'23, 6:00 pm)

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has further alerted the people in power as to the importance of biosafety measures.⁸ The world had not imagined as was not equipped to tackle such a situation as it could not fathom the perils of biotechnology.

BIO SAFETY GOVERNANCE IN INDIA

India as country has been an active participant in making rules and laws related to biosafety. India was quick in understanding biosafety, its importance and need and in further taking adequate steps for the same. India is in fact one of the first countries to have a separate government department for biotechnology, it is called the Department of Biotechnology and comes under the Ministry of Science and Technology.⁹

The following legislations are in place in India to achieve the objective of biosafety:

❖ CONVENTION ON BIOLOGICAL DIVERSITY

The Convention on Biological Diversity (CBD) is the international legal instrument for "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources". Its objective is to encourage actions that will lead to a sustainable future. It has been ratified by 196 nations.¹⁰

The Convention was opened for signature at the Earth Summit in Rio de Janeiro on 5 June 1992 and entered into force on 29 December 1993. It is the Multilateral Environmental Agreement (MEA) which is the source of international law on biosafety. One of its supplementary agreements is the Cartagena Protocol.

India became a party to the convention on February 18, 1994.

Among the articles in its text, Article 19 specifically deals with the 'Handling of Biotechnology and Distribution of its Benefits'.

It says:

1. "Each Contracting Party shall take legislative, administrative or policy measures, as

⁸ *Supra note 1*

⁹ Department of Biotechnology, Ministry of Science and Technology, GOVERNMENT OF INDIA (Last visited 5th June'23, 4:00 pm) <https://dbtindia.gov.in/about-us/introduction>

¹⁰ *Convention On Biological Diversity, Key International Instrument For Sustainable Development*, UNITED NATIONS (Last visited 6th January'23) available at <https://www.un.org/en/observances/biologicaldiversityday/convention#:~:text=The%20Convention%20on%20Biological%20Diversity,been%20ratified%20by%20196%20nations.>

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appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.”¹¹

❖ THE CARTAGENA PROTOCOL ON BIOSAFETY

The Cartagena Protocol on bio safety is supplementary to the Convention on Biological Diversity. It is also known as (CoP-MoP 6).

The Protocol was adopted in 2000 and it came into force in 2003. The protocol was adopted in Montreal in 2000.

The Cartagena Protocol on Biosafety is the first international agreement that aims to regulate transboundary movements of Genetically Engineered (GE) organisms. The increase in globalisation and the mobilisation of the international community called for precautions to be taken with respect to movements. ¹²

¹¹ Convention on Biological Diversity, Article 19

¹²Ms Kavithakuruganti vs Ministry Of Environment & Forests, CIC/SA/A/2015/901798

The Cartagena Protocol on Biodiversity seeks to protect biodiversity from the potential risks caused by LMOs created by modern technology.

The tremendous advancements in biotechnology and associated concerns called for the need for adoption of this protocol.

The international protocol is concerned with the movement of LMOs (living modified organisms) resulting from modern technology from one nation to another.

India is also a party to the Cartagena Protocol (ratified in 2003). The competent authority in the country for the implementation of the Protocol is the Ministry of Environment, Forest and Climate Change (MOEF&CC), Government of India.

India was one of the early movers as back in 1989, it took steps for development of biosafety framework in the country by introducing the Biosafety Rules, 1989. This helped in achieving control over movement of LMOs and created a systematic structure for the same.

The Protocol also has provisions for an Advance Informed Agreement (AIA) procedure, it is one of its most appreciated procedures. The AIA is mainly aimed at ensuring that the countries are given a sufficient opportunity to understand and analyse before taking a decision about importing LMOs in their country.

There are four components to the AIA:

- Notification by the exporter
- Acknowledgement of notification receipt by the importer
- Decision procedure
- Review of decisions

The Cartagena Protocol also sets up a Biosafety Clearing-House (BCH) to enable information exchange on LMOs between countries. The BCH is an information-sharing mechanism for relevant technical, scientific and legal information to create an environment of ease for the participating nations and ensure smooth exchange of required information.¹³

¹³*Supra note 4*

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The Protocol gives a precautionary approach to the issue of transfer of LMOs from one country to another.¹⁴ It ensures that nations err on the side of caution when dealing with biotechnology.

✧ ENVIRONMENT PROTECTION ACT, 1986 AND BIOSAFETY RULES 1989

The Environment (Protection) Act was enacted in the year 1986. The main objective for which it was enacted was to provide for the protection and improvement of environment and matters concerned with it.

This act does not directly deal with the issue of biosafety, it empowers the government to make related laws.

Three provisions of the Environment Protection Act form the basis of the biosafety regulations in the country. These are sections 6, 8, and 25 of the Environment Protection Act 1986.¹⁵

> While Section 6¹⁶ of the Act empowers the Central Government to make rules on procedures, safeguards, prohibition and restrictions for handling of hazardous substances,

> Section 8¹⁷ of the Act prohibits a person from handling hazardous substances, except in accordance with procedures and after complying with safeguards.

> Section 25¹⁸ of the Environment Protection Act empowers the Central Government to lay down rules regarding procedures and safeguards for handling hazardous substances.

India has also adopted the Biosafety Rules, 1989. These originated from the Environment Protection Act, 1986. They apply to manufacture, import and storage of micro organisms and gene-technology products and include products made of micro organisms that are genetically engineered.¹⁹

✧ BIOLOGICAL DIVERSITY ACT, 2002

It is an Act that was enacted and put in place in 2002 as India's domestic law for the convention of Biological Diversity. It aims at conservation of biological resources and works

¹⁴ *Cartagena Protocol on Biosafety*, BYJUS (Last visited 5th May'23, 3:00 pm) available at: <https://byjus.com/free-ias-prep/cartagena-protocol/>

¹⁵ A. Damodaran, 'Re-Engineering Biosafety Regulations In India: Towards a Critique of Policy, Law and Prescriptions', 1/1 Law, Environment and Development Journal (2005), p..

¹⁶ Environment Protection Act 1986, §6

¹⁷ Environment Protection Act 1986, §8

¹⁸ Environment Protection Act 1986, §25

¹⁹ *Supra note 11*

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towards use of biotechnology and these resources in a sustainable manner so as to limit the harm to the environment by the maximum extent possible.²⁰

It aims at ensuring equitable distribution of benefits arising from the use of the before mentioned biological resources.

- Three regulatory bodies have been formed under this act:
 - > The National Biodiversity Authority (NBA)
 - > The State Biodiversity Boards (SBBs)
 - > The Biodiversity Management Committees (BMCs) (at local level)

These authorities have been empowered by grant of funds and have the authority to give their approvals for the activities related to use of biological resources as has been elaborated in the Act.

✧ Further to introduce a systematic structure to ensure safety from the use of Genetically Modified Organisms (GMOs) and products thereof in research and application to the users as well as to the environment, a three tier mechanism comprising Institutional Biosafety Committees (IBSC) at the Institute/ company; the Review Committee on Genetic Manipulation (RCGM) in the Department of Biotechnology; and the Genetic Engineering Approval Committee (GEAC) in the Ministry of Environment & Forests (MoE&F) for granting approval for research and development activities on restructured DNA products and monitoring and evaluation of research activities involving modern biotechnology has also been established.²¹

CASE LAWS

1) **Aruna Rodrigues & Others v. Union of India, 2012**²²

This is a landmark judgement related to biosafety in India.

²⁰ Biological Diversity Act, 2002, IPLEADERS (Last visited 6th January'23) available at: <https://blog.ipleaders.in/overview-biological-diversity-act-2002/>

²¹ *Biosafety Programme*, Government of India (Last visited 6th January'23) available at: <https://dbtindia.gov.in/regulationsguidelines/regulations/biosafetyprogramme#:~:text=Under%20Biosafety%20Research%20programme%20main,research%20and%20application%20to%20the>

²² *Aruna Rodrigues & Others v. Union of India*, (2012) 5 SCC 331

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The petitioners, stated that a grave and hazardous situation, raising biosafety concerns, was developing in our country due to release of Genetically Modified Organisms ('GMOs'). The GMOs were allowed to be released in the environment without proper scientific examination of biosafety concerns affecting both the environment and human health.

Thus, the petitioners filed a Public Interest Litigation (PIL) before the Supreme Court of India praying that a protocol be put in place that shall require scientific examination of these products of biotechnology and their release be permitted only on passing the scientific criteria.

It was contended by the petitioners that confidence in the biosafety law and its implementation can only come with transparency in results of GM research and when the results of scientific testing and of a particular GM product analysis are made public. They contended that the process of decision-making had to be open for public scrutiny. Accessibility to information from public authorities was an essential element of putting adequate rules in action.

The Supreme Court after much discussion and deliberation ordered setting up of a Technical Expert Committee which would review and recommend the nature of sequencing of risk assessment (environment and health safety) studies that needed to be done for all GM crops before they were released into the environment.

2) Ms. Kavithakuruganti v. Ministry Of Environment & Forests on 1 April, 2016²³

In the present case, the appellant has filed an Right to Information (RTI) application seeking copy of biosafety document of GM Mustard being experimented in fields in India along with raw data of studies conducted. The concerned authority that is the Central Public Information Officer (CPIO) said that information could not be given as it was under process.

The appellant filed appeal before the first appellate authority (FAA). FAA upheld that the information was covered under section 8 (1) (d) of the RTI act which would breach commercial confidence of a third party, Centre for Genetic Manipulation of Crop Plants. They also claimed that the trial was premature. Hence, she was denied the information that she sought through the RTI.

²³ Ms. Kavithakuruganti v. Ministry Of Environment & Forest, CIC/SA/A/2015/901798

Aggrieved, the appellant filed second appeal before the Central Information Commission.

In this case, the provisions of the Cartagena Protocol on Biosafety were studied and it was observed that Article 21(3) secured confidential information. It goes as follows:

“Each party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.”

However, Article 21(6) of the protocol provides for what should not be considered as confidential:

- (a) The name and address of the notifier;
- (b) A general description of the living modified organism or organisms;
- (c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking into account risks to human health too.
- (d) Any methods and plans for emergency response.

It was held by the Central Information Commission (CIC) that the public authority shall disclose the information as explained under Article 21(6) of the Protocol which cannot be considered as confidential after avoiding confidential information if any. It also directed all biosafety data pertaining to all other GMOs in pipeline be disclosed as voluntary information.

3) Prashant Sahebrao Jadhav v. University Grants Commission on 25 July, 2022²⁴

The Appellant filed an RTI Application dated 21.12.2020 seeking information related to biosafety supervisors. On not being provided by the information, he filed a first appeal but on receiving an unsatisfactory reply he filed a second appeal before the Central Information Commission.

²⁴ Prashant Sahebrao Jadhav v. University Grants Commission, CIC/UGCOM/A/2021/605432

The Respondent in this case submitted that information sought with respect to Biosafety Supervisors in the instant RTI Application pertained to a third party and disclosure of such personal information would cause unwarranted invasion of their privacy. Hence, the disclosure of the said information is exempted under section 8(1)(j) of the RTI Act. He furthermore submitted that the requisite information sought by the Appellant is held by their office in fiduciary relationship which is exempted from disclosure under section 8(1)(e) of the RTI Act since the appointments of Biosafety Supervisors were done on temporary basis through a private agency.

The Central Information Commission held:

So far as information with respect to sharing Educational Qualifications of Biosafety Supervisors, the Commission was of the opinion that there is no exemption for sharing the information about how much they are qualified and the same can be disclosed since they are working in a public institute. Hence, the Commission deemed it appropriate to direct the present Central public Information Officer (CPIO) to provide a revised reply by communicating the relevant information with respect to Educational Qualifications of Biosafety supervisors as sought for in the instant RTI application.

CRITICAL ANALYSIS AND CONCLUSION

The Cartagena Protocol on Biosafety and the other acts as discussed above contains many important principles like the precautionary principle which are now a part of the International law which have been adopted by various countries throughout the globe. The development of modern technology has proved that this protocol is a very important piece of legislation required to protect the world from the negative effects of creation of GMOs and LMOs.

However, these are texts which are not free from deficiencies. The legislations are not whole in the sense of it being enough for meeting the needs keeping in mind the current environment related to biosafety and bioterrorism. This calls for the need for National governments to have their own stringent laws in place to make up for the deficiencies in the International Protocols. For instance, one major drawback of the Cartagena protocol is that it does not provide for civil liability and redresses if damage occurs due to the release of genetically engineered organisms and products.

The law on biosafety in India is still developing. It is clear from the study of the legislations in place that the country is not taking the threat of biotechnology lightly, but there is still a need to have a full fledged law regulating bioengineering in the country. Further, people also need to be made aware of the fact that they can demand transparency in the use of biotechnology, so that as concerned citizens they can raise questions when there is a threat to the community and the environment.

Though there is a long road ahead, regulations like the Cartagena Protocol are testament to the progress we have made in achieving the aim of biosafety.²⁵



²⁵AARON COSBEY, *The Cartagena Protocol on Biosafety: An analysis of results*, International Institute for Sustainable Development, available at <https://www.iisd.org/system/files/publications/biosafety.pdf>

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