BIOSAFETY LAWS IN INDIA AND PAKISTAN: A COMPARATIVE STUDY

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ABSTRACT

Biosafety is a term that encompasses the process of preventing biological harm to the environment and human health. The study of microorganisms and pathogens knows no bounds, and even minor tampering could cause major disturbance in humans. Many of the people who undertake such study are not trained in biology; instead, they may be physicists, engineers, or chemists, which makes conducting research on such a subject difficult. Scientists are responsible for doing responsible science since they have a responsibility to the entire society, and so conscientious steps from their end are a must for research. The World Health Organization (WHO) has played a key role in developing laws and regulations for laboratory-based research on microorganisms, as any sort of neglect could result in a dangerous situation. India and Pakistan are two of the few Asian countries with biosafety systems in place. However, the lack of openness in these policies causes consumers to have unwarranted misgivings. However, comprehensive risk assessment approaches are required because laboratory research is limited in a context where such germs could be employed for weaponization. The researcher has examined the institutional structures in both countries, as well as their shortcomings and proposed alternatives, in this study.

***Keywords*:** biosafety, comparative study, GMO, DNA

I. Introduction

BIOSAFETY IS a term used to describe the process of preventing biological harm to the environment and human health. Its purpose is to safeguard biological creatures, particularly genetically modified organisms (GMOs). GMOs are being introduced for the benefit of people, but it is unclear when they can become a biohazard. Any manipulation of germs can result in

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the death of countless people[1]. Covid 19 pandemic is one such biohazard produced in the laboratories. Therefore, proper rules, regulations, and structure for biosafety in a nation are of utmost importance[2]. Biosafety is based on three very basic yet important principles of protection, surveillance, and control. Laboratory Biosafety means the various principles, practices, and techniques to contain the unwanted exposure of pathogen and toxins from the labs[3]. The World Health Organization (WHO) has played a key role in developing laws and regulations for laboratory-based research on microorganisms, as any sort of neglect could result in a dangerous situation. The Cartagena Protocol explicitly establishes biosafety norms, which must be followed in current science research. The Biological Weapons Committee (BWC), where such matters are resolved through discourse, is another pivot in this regard.

The WHO has created four biosafety levels for various combinations of laboratory practices, safety equipment, methodologies, and other factors. The BS-1 criteria must be observed in the basic teaching labs. The BS-2 standard will be adopted in research and diagnostic research facilities. The BS-3 standards are used by highly specialized diagnostic services, and the BS-4 standards are used by labs that handle harmful infections and poisons[4]. These recommended levels are devised for the conditions in which the agents are to be safely handled. There is even a classification devised by WHO of the microorganisms which formulate various **risk groups** for the lab work[5]. This is completely based on the relative health hazards posed by the organisms. The classification is as follows:

1. **Risk Group 1**: Negligible or low individual and societal risk.
2. **Risk Group 2**: Limited individual risk and low societal risk.
3. **Risk Group 3**: High individual risk and low societal risk.
4. **Risk Group 4**: High individual and societal risk[6].

[1]Biosafety Manual for Public Health Laboratories by Ministry of Health, India, *available at:* http://www.cghealth.nic.in/cghealth17/Information/content/NipahVirus/Biosafety_Manual.pdf (last visited on November 4, 2023).

[2] Jenson Samraj, "Emerging Biosafety Materials from the Covid-19: A review from its material from Environmental Perspective", Academia, *available at:* file:///C:/Users/Admin/Downloads/Manuscript_Jenson_Samraj-with-cover-page-v2.pdf. (last visited on November 3, 2021).

[3] Aarti Gupta, "Governing Biosafety in India: The Relevance of the Cartagena Protocol", Belfer Center for Science and International Affairs, *available at*: https://www.belfercenter.org/publication/governing-biosafety-india-relevance-cartagena-protocol (last visited on November 4, 2021).

[4]The Laboratory Biosafety Manual by WHO, *available at*: https://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf (last visited on November 3, 2021).

[5]Classification of Organisms by Risk Group by University of Tasmania, *available at*: https://www.utas.edu.au/research-admin/research-integrity-and-ethics-unit-rieu/biosafety/risk-groups (last visited on November 2, 2021)).

[6] *Id.*, at 2.

A process of **Risk Assessment** is followed in order to identify various infectious or potentially infectious agents or organisms which can cause a Laboratory Associated Infection if exposed[7]. There are various factors which are considered for the purpose of risk assessment such as:

1. Risk Groups
2. Pathogenicity or infectious dose of the agent
3. Potential outcome, if exposed
4. Natural route of infection
5. Other routes of infection
6. Stability of the agent
7. Presence of host
8. Information available
9. Lab activity
10. Genetic manipulation
11. Endemicity of the organism[8].

The risk assessment is aided, performed, and reviewed by the Institution Biosafety Officer or the Institution Biosafety Committee.

Biosafety legislation has been attacked by environmentalists and industry alike. Industries argue that the lack of a clear framework has instilled unnecessary skepticism in the general public about GMOs. In addition, the DBT works with firms on an individual basis. This makes it impossible for industries to submit their cases as a group. On the other hand, industries gain from this. They are not required to take a public stance on any transgenics discussions, for example. Furthermore, the lack of clearly defined rules allows business to have a greater say in how recommendations are developed and implemented.

II. Biosafety Laws in India

India is among the few Asian countries which have institutionalized biosafety mechanisms. In November 1996, a symposium was organized in partnership with the United States Department and the Indian Institute of Management, focusing on 'Biotechnology and Biodiversity: Scientific and Ethical Issues.' During this event, there were in-depth discussions concerning

[7] *Supra* note 3 at 2.
[8] *Supra* note 5 at 2.

the development of policies, involvement of the public, and establishment of monitoring systems for biosafety governance in India.[9] India is highly involved in the lab and field projects on Genetically Modified Organisms and therefore effective enforcement of the biosafety rules is the need of the hour. In the symposium, unauthorized trial on transgenic fields were revealed where at the compound of Indian Agricultural Research Institute only nets were used as the only protection from the experimental area[10]. This was a complete violation of the biosafety guidelines and as a result in December, 1996, IARI had been ordered by the government to burn their experimental plot. India has a total of two acres of transgenic fields where Department of Biotechnology had conducted two field trials. Apart from these trials, there are many glasshouse experiments conducted in Gurgaon, India[11]. The increase in glasshouse trials implies an increase in the field trials as well. Therefore, a proper institutionalized mechanism is the need of the hour for a safe laboratory research on biological agents[12].

India has various legislations drafted for biosafety which are as follows:

1. Under the Environmental (Protection) Act of 1986, rules regulating the manufacture, use, import/export, and storage of hazardous microorganisms/genetically modified organisms or cells were established in 1989. The Ministry of Environment and Forests (MoEF) has issued these regulations, which control GMO research and large-scale applications across the country. Hazardous microorganisms (including diseases) are also included under the scope of this Act, as are genetically modified organisms[13].
2. The Plant Quarantine (Regulation of Import into India) Order, 2003, lays out the various requirements for importing plants into India. It expressly specifies that plant materials listed in Schedule IV of the order are not permitted to be imported into India. For importing GMOs, germplasm, microbiological cultures, and other items as specified in

[9] Sachin Chaturvedi, "Biosafety Policy and Implications in India", 30 *Journal of Biotechnology and Development Monitor* 1013 (1997).
[10] A Damodaram, "Re-engineering Biosafety Regulations in India: Towards a critique of Policy, law and Prescriptions", 1 Journal of Law Environment and Development Journal 1, (2005).
[11] *Supra* note 5 at 2.
[12] *Supra* note 3 at 3.
[13] The Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms Genetically Engineered Organisms or Cells Rules, 1989 Notification, *available at:* http://nbaindia.org/uploaded/Biodiversityindia/Legal/28.%20Rules%20for%20the%20manufacture,%20use%20import%20export%20and%20storage%20of%20hazardous%20microorganism%20genetically%20engineered%20organisms%20or%20cells,%201989.pdf (last visited on December 31, 2021).

the order, appropriate approvals must be obtained. In the Order, there are different norms and regulations regarding post-entry quarantine of plants and seeds[14].

3. Food Safety and Standards Act, 2006[15] this Act has formed the Food Safety and Standards Authority of India, which is involved in laying down numerous science-based standards and techniques for food and its manufacture, distribution, sale, import, and availability, among other things[16].

A. Institutionalized Mechanism

India's Biosafety and Recombinant DNA Guidelines of 1990 are the policies proposed and adopted by the government under the Environmental Protection Act, 1986, to avoid the potential risk from the Genetically Modified Organisms to the environment and public health[17]. They aim to regulate the rDNA research with the organisms that have negligible or low harmful effects. They help in minimizing the several possibilities for the occasional release of the agents and ban such a release which poses a potential threat to the environment[18]. In 1994, India joined the Biodiversity Convention as a signatory. They soon changed the above-mentioned standards and created new regulations for the safe handling of genetically modified organisms in research, technology transfer, and application activities. There are rules for their safe shipment and transfer, as well as for their sale and deliberate release[19].

The implementation of the above stated regulations is conducted by some ad hoc committees which are:

1. Institutional Biosafety Committees (ISBC)
2. Review Committee on Genetic Manipulation (RCGM)
3. Genetic Engineering Approval Committee (GEAC)

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[14] Plant Quarantine Order (Regulation of Import into India), 2003 by Food and Agriculture Organization of the United Nations, *available at:* https://www.fao.org/faolex/results/details.en/c/LEX-FAOC149142/#:text=Plant%20Quarantine%20Order%20(Regulation%20of,countries%20listed%20in%Schedule%2DIV (last visited on December 31, 2021).

[15]Indian Laws and Regulations, Indian Council of Agricultural Research Biosafety Portal, *available at:* https://biosafety.icar.gov.in/category/indianlawsandregulations/ (last visited 3rd November, 2021).

[16]Food Safety and Standards Act, 2006, *available at:* https://www.indiacode.nic.in/handle/123456789/2027?sam_handle=123456789/1362#:text=An%20Act%20to%20consolidate%20the,and%20wholesome%20food%20for%20human (last visited 31 December, 2021).

[17] *Supra* note 5 at 4.

[18] *Ibid.*

[19] *Supra* note 3 at 4.

4. Recombinant DNA advisory Committee (RDAC)[20].

These committees have the statutory authority for the implementations of the policies. The members of these committees are appointed by the Department of Biotechnology and mostly consist of the members of the scientific community and the staff of DBT and the members from the Ministry of Environment and Forestry[21].

Institutional Biosafety Committee: It is a committee which is duly established in every institution which conducts rDNA research or production activities in order to monitor the activities at the institutional level itself. The constitution of the committee consists of the head of that institute, three scientists, one medical officer and a person nominated by the Department of Biotechnology[22]. In its role, the entity ensures the diligent reporting of safety guideline implementation, accidents, risks, and deviations to the RCGM. It provides medical assistance to laboratory personnel when needed. Additionally, it evaluates and approves proposed guidelines for new projects, devises emergency plans, and grants permission for biosafety research endeavors.[23]

Review Committee on Genetic Manipulation: Department of Biotechnology, Council for Scientific and Industrial Research, Indian Council for Medical Research, Department of Science and Technology, and Indian Council of Agricultural Research are all members of this body[24]. In its pivotal role, the entity conducts thorough risk assessments for lab and field research. It determines appropriate containment policies for experiments involving hazardous microorganisms. Additionally, it offers guidance on Intellectual Property matters and advises customs authorities on Genetically Modified organisms and biological materials. The entity conducts safety inspections of various labs and supports the Bureau of Indian Standards (BIS) in developing standards for rDNA technology products.

[20]National Law School of India University, "Biosafety Regulatory framework in India", *available at:* http://nlsabs.com/wp-content/uploads/2018/03/Biosafety-Regulatory-Framework-India1.pdf (last visited on November 2, 2021).
[21] *Supra* note 5 at 4.
[22] Institutional Biosafety Committee, Ministry of Science and Technology, *available at:* https://dbtindia.gov.in/regulations-guidelines/regulations/biosafety-programme (last visited on November 3, 2021).
[23] *Supra* note 5 at 4.
[24] Government of India, "Report of the Review Committee on Genetic Manipulation" (Ministry of Science and Technology).

Genetic Engineering Approval Committee: The Department of Environment and Forests oversees this committee. The State Biotechnology Coordination Committees and District Level Committees help them. It allows for the usage of genetically modified organisms as well as rDNA products. In its crucial role, the entity grants approvals for importing, exporting, producing, transporting, and selling genetically engineered organisms (GEOs). It also authorizes the release of GEOs into the environment and oversees their large-scale use. Diligently monitoring GEO usage in field and lab research, it evaluates potential risks to ensure safe and responsible practices.[25]

Recombinant DNA advisory Committee: The Department of Biotechnology oversees forming this body, which is overseen by the Ministry of Science and Technology. It oversees supplying the implementation committees with a regulatory framework[26].

Role:

1. It conducts meetings once in every six months or sooner to discuss the policies and standards of the safety regulations.
2. These meetings help to devise long term policies and regulations, to formulate new safety guidelines and train the researchers and other people involved about the potential risks and threats[27].

B. Loopholes in Present Laws

The lack of transparency in these policies leads to unnecessary doubts in the minds of the people. One of the major drawbacks of these policies is the case-to-case basis approach taken by the Department of Biotechnology[28]. This gives unnecessary and unwanted advantage to the industries involved. They don't have to take any public stand in case of controversies and moreover the unclear guidelines help them to influence the decisions. There are various criticisms about the whimsical regulations and policies devised by the authorities which need amendments. The Environmental Organizations such as the Gene campaign and Research

[25] *Supra* note 3 at 4.
[26] Recombinant DNA Advisory Committee, Department of Biotechnology, Ministry of Science and Technology, Government of India, *available at:* https://dbtindia.gov.in/regulations-guidelines/regulations/biosafety-programme (last visited on November 3, 2021).
[27] *Supra* note 3 at 4.
[28] *Ibid.*

Foundation for Science Technology and Ecology have criticized the policies on the ground that it is not relevant to the needs of India's environmental concerns.

India has certain regulations completely adopted from the US Legislations. These legislations are not very effective in the Indian scenario as India is a biodiversity rich country whereas USA has a poor biodiversity[29]. The effectiveness of biosafety laws can vary between countries due to their distinct socio-economic, environmental, and cultural contexts. What might work well in one country may not be directly applicable to another, emphasizing the need for tailored regulations that address specific challenges and requirements of each country. India's unique biodiversity and diverse agricultural landscape necessitate specialized regulations to manage the risks associated with GMOs used in its agriculture.

Moreover, public attitudes towards GMOs and biotechnology differ significantly across countries, and India's cultural and social factors can influence the acceptance and perception of GMOs. Therefore, while framing biosafety laws, it is essential to consider these local factors to ensure public acceptance. Involving local stakeholders, such as farmers, scientists, environmentalists, and civil society organizations, in the policymaking process is vital to garner broader acceptance and ownership of biosafety laws. Their input can contribute to more effective and well-rounded regulations that align with the needs and concerns of the Indian population.

There is also a lack of infrastructure, finance, facilities, and expertise in India. Their experience is also limited to small field trials and therefore this creates several doubts regarding them, successfully conducting bigger projects and preventing other risks from GMO's[30]. Despite backlogs in domestic biosafety policy and enforcement, India must also deal with these challenges on a global scale. International recommendations for the safe use of GMOs have been released by the United Nations Environment Programme (UNEP) and the World Health Organization (WHO). Under the Convention on Biological Diversity, the UNEP is drafting a "Protocol on Biosafety." This procedure incorporates public engagement by making the results of any GMO testing and monitoring available to the public.

[29] Zahoor Ahmed, "National Implementation of the Biological Weapons Convention: The Case of India and Pakistan", Vertic Media, *available at*: http://www.vertic.org/media/assets/nim_docs/background%20articles/BWC_Ahmed_2010.pdf (last visited on November 4, 2021).
[30] *Supra* note 5 at 4.

This, however, has not been implemented in Indian policy. Parts of the OECD's risk evaluation criteria have been incorporated into the Indian rules. Some Indian businesses believe that the approach taken is overly cautious and does not adhere to the familiarity principle in biosafety evaluation[31]. The guidelines devised by India lacks the familiarity principle[32] which means to make available the knowledge and experience to the country regarding the testing involved. In view of the various commitments India has made in the international forum, it is necessary for the country to review the mechanisms that the country follows now.

Biosafety laws play a crucial role in protecting the environment from any unintended negative consequences that may arise from the release of genetically modified organisms (GMOs). Amending these laws can strengthen measures aimed at preserving biodiversity, ecosystems, and natural resources, thus reducing any potential adverse impacts. To ensure the safety of GMOs intended for human consumption or agricultural use, it is essential for them to undergo rigorous evaluations. By updating biosafety laws, the oversight of GMOs used in food and agriculture can be improved, ensuring their safety for both human health and the environment. The process of amending biosafety laws can lead to increased transparency in the decision-making process for biotech research and applications. Involving the public in this regulatory process fosters a better understanding and acceptance of biotechnology while addressing any concerns they may have. To ensure the effectiveness of biosafety laws, robust monitoring and enforcement mechanisms need to be put in place. Amending these laws can enhance the capabilities of regulatory bodies in overseeing compliance and taking appropriate actions in cases of biosafety guideline violations.

III. Biosafety Laws in Pakistan

Pakistan is a terror-stricken country because of which the threat of bioterrorism is also huge. There are threats posed to national security due to this and therefore Pakistan has a series of legislations devised for biosafety[33]. In Pakistan, the National Laboratory Biosafety and Biosecurity Policy was drafted with a notification by the Ministry of National Health Services

[31] *Supra* note 4 at 4.
[32] *Supra* note 3 at 3.
[33] Ali Talia Khalil, Faouzia Tanveer, *et.al*., "Pakistan's Bio-preparedness with regard to Biosecurity, Biodefense Strategies and Policy Measures", 6 *Journal of Bioterrorism and Biodefense* 61 (2015).

Regulations and Coordination and developed by the National Laboratory Working Group. The policies have been drafted on a consensus-based approach by national, international technical experts, microbiologists, public health specialists and so on from both the public and the private sector[34].

What government agencies are in charge of high-containment biological (high BSL) laboratory' safety and security?
The Disarmament Division, the Ministry of Foreign Affairs, and the National Biosafety Committee are among the entities responsible. In addition, the Pakistan Biosafety Rules 2005 mandate the formation of Institutional Biosafety Committees and the designation of a Biosafety Officer for organisations engaging in biotechnology or genetic manipulation.

In the event that a country possesses BSL (Biosafety Level) laboratories, are there specific and well-defined criteria used to make decisions?
a. Should such facilities be established or not?
b. What criteria are utilised to decide where such facilities should be located?
c. What criteria are used to determine which research will be carried out at these facilities?
d. When it comes to making judgments, what scientific, technical, and management advice is accessible to governments?

Pakistan has various legislations and various national initiatives have also been formulated for better implementation and effectiveness of biosafety rules and regulations in the country[35]. The various legislations drafted or ratified by Pakistan are:

1. **Biological Toxin Weapon Convention**: It was signed by Pakistan in 1972. They are strongly committed to the rules and regulations laid down in this Convention. They have drafted several legislations after being a signatory to this Convention such as the Drugs Act 1976, Plant Quarantine Act 1976, Animal Quarantine Act 1979, Anti-Terrorism Act 1997, Environmental Protection Act, 1997, Pakistan Export Control Act 2004 and Pakistan Penal code and also Biosafety rules and Biosafety guidelines[36].
2. Pakistan is also a signatory to the **Cartagena Protocol, 1992**.

[34]National Biosafety Systems, UPMC Center for Health Security, *available at:* https://www.hsdl.org/?view&did=794118 (last visited on November 4, 2021).
[35] *Supra* note 3 at 8.
[36] *Ibid.*

3. **Pakistan Biosafety Rules, 2005**: these rules deal with the storage, transportation and manufacturing of the microorganisms and their gene products for any research to be conducted by the research institutes. It also deals with the export, sale or purchase of the living modified organisms[37].
4. **National Biosafety Rules, 2005**: This provides for an institutionalized mechanism for the biosafety governance in Pakistan. It devises rules for the deliberate release of the GMO's from laboratories which could have a detrimental effect on human health and ecology. The regulatory bodies to monitor and conduct these tests include Institutional Biosafety Committee (IBC), Technical Advisory Committee (MBC), and National Biosafety Committee (NBC)[38].

A. Institutionalized Mechanism

The National Biosafety Rules, 2005 provides for an institutionalized mechanism for the biosafety governance in Pakistan. These guidelines were developed to avoid possible undesirable effects arising from laboratory work on recombinant DNA and deliberate release of GMOs and their products on human health and environment including regulations for conducting laboratory and field work as well as procedure for approval of GMOs for commercial use[39].

These rules are monitored and regulated by three committees which are:

1. Institutional Biosafety Committee (IBC)
2. National Biosafety Committee (NBC)
3. Technical Advisory Committee (TAC)

Institutional Biosafety Committee: this committee is constituted by the head of the institute and the composition of this committee is that The Chairperson of the Committee is the head of the institution. The members of the committee include the subject experts, social scientists or the economists and the civil society representatives[40]. The role of this entity is multifaceted and involves providing assistance and support to various committees and researchers to ensure biosafety guidelines are followed throughout the research process. They work closely with the National Biosafety Committee (NBC) and the Technical Advisory Committee (TAC) to facilitate decision-making and

[37] *Ibid.*
[38] *Ibid*.
[39] *Ibid.*
[40]The Pakistan Biosafety Rules, 2005, s. 8.

evaluate the qualifications of researchers. Additionally, this entity plays a crucial role in monitoring ongoing research activities within the institute, maintaining an updated directory of all individuals involved in the research, and ensuring the health and safety of lab and field workers.

They are responsible for determining additional safeguards and operating instructions required for safe research practices involving genetically modified organisms (GMOs) and living modified organisms (LMOs), especially concerning imports, use, manufacture, and transportation. In cases where biosafety guidelines are violated, this entity has the authority to take necessary actions, such as withholding funds or using administrative measures to address the issue. They also implement institutional emergency response plans to handle unforeseen situations.

Furthermore, they diligently assess all research projects submitted to them and keep a record of approved projects. Collaborating with research teams, they undertake risk assessments to ensure that potential hazards are identified and mitigated appropriately[41].

National Biosafety Committee: This committee is established by the Federal Government by a notification and it consists of the Secretary of Ministry of Environment as the Chairperson and several other representatives of the Ministry of Food and Agriculture, health, Education and so on as the members. The Chairperson of NBC is the Director General of Pakistan EPA. The Committee drafts its own rules and regulations and conducts meetings which should not be less than four in a year[42].

This entity plays a crucial role in establishing and maintaining the safety standards and procedures concerning genetically modified organisms, specifically living modified organisms (LMOs). One of its key responsibilities is to conduct risk assessments for LMOs and determine appropriate labelling requirements to ensure transparency and awareness among the public. When it comes to safeguarding human health and the environment, this entity has the authority to impose bans or restrictions on the import, export, sale, or trading of LMOs that are found to pose significant risks. Recognizing the importance of international standards, this entity

[41] *Supra* note 40, s. 9.
[42] *Supra* note 40, s. 4.

actively engages with international biosafety committees and other relevant agencies to ensure that Pakistan aligns with global norms in biosafety practices.

To enhance compliance and adherence to biosafety guidelines, this entity restricts any individual, authority, or institution from disregarding the advice provided by the Technical Advisory Committee (TAC). In addition to overseeing genetic manipulation activities at all levels, this entity facilitates the exchange of technical expertise to promote knowledge sharing and best practices within the scientific community. A major part of its role involves coordinating with the Institutional Biosafety Committee (IBC) and creating awareness about biosafety rules and regulations among stakeholders and the general public.

In the interest of maintaining safety levels, this entity acts as a liaison between government bodies and private organizations, fostering collaboration and cooperation in matters related to biosafety. Through these efforts, the entity aims to ensure that biosafety remains a top priority in all aspects of genetic research and applications in Pakistan[43].

Technical Advisory Committee: This committee is established by the Federal Government by a notification and it consists of Director General of Pakistan's Environment Protection as the Chairperson and Director of the National Institute for Biotechnology and Genetic Engineering as the Vice Chairperson and 13 other members[44].

The primary responsibility of this entity is to carefully assess and evaluate applications related to genetically modified organisms (GMOs) and determine whether to grant permission for laboratory or field work. They play a critical role in the decision-making process by advising the National Biosafety Committee (NBC) on whether the proposed research meets the necessary safety standards. In addition to examining applications, this entity also oversees and regulates the large-scale use of GMOs to ensure that all activities are conducted responsibly and in compliance with biosafety guidelines.

A significant part of their role involves reviewing the methodologies used in GMO research and the manipulation of DNA to guarantee that scientific investigations are conducted with

[43] *Supra* note 40, s. 5.
[44] *Supra* note 40, s. 6.

precision and adherence to ethical principles. Moreover, they take on the crucial responsibility of monitoring the release of genetically engineered organisms into the environment. This task involves careful observation and evaluation to ensure that potential risks are identified and mitigated appropriately.

To support the NBC in making informed decisions about industrial production and cases involving risk and safety, this entity provides valuable information and surveillance data. Their involvement does not end with granting permissions; they also supervise the implementation of terms and conditions set forth by the NBC. This ensures that research activities and other actions related to GMOs are carried out according to the established guidelines and regulations. In summary, this entity serves as a pivotal gatekeeper in the field of GMO research and implementation, working diligently to maintain a delicate balance between scientific progress and the protection of human health and the environment[45].

B. Loopholes in Present Laws

There is a need for comprehensive risk assessment approaches since laboratory research is limited in a setting where a virus could be used for weaponization. Accurate and ongoing assessments of potential bioweapons are required before effective policies to address the dangers can be developed[46]. The ideal technique for effective implementation of rules and regulations is said to be a law-based approach. As a result, there is a pressing need in Pakistan for legislation such as the Biodefense Act and others. By proposing policy recommendations to the government, the scientific community can help to strengthen the many laws that have been developed[47]. Because of the recent concerns posed by the use of biological materials for bioterrorism, more emphasis should be placed on the development of effective response mechanisms such as quick illness surveillance and epidemic control. Furthermore, research should be focused on biodefense in order to create vaccines and treatments[48].

[45] *Supra* note 40, s. 7.
[46] *Supra* note 3 at 8.
[47] *Ibid.*
[48] *Supra* note 33 at 8.

IV. Indo-Pak Relations and an Opportunity for Mutual Learning

Pakistan has ratified a number of international biological treaties, including the BTWC, CWC, WTO, CBD, and UN Resolution 1540, to address major biological threats and promote the peaceful application of biological research. National legislation aiming at strengthening biosecurity and biosafety includes the Export Control Act, the Environmental Protection Act, the National Biosafety Guidelines, and the National Biosafety Center (NBC). Despite these policy attempts, Pakistani professionals have a poor understanding of biosafety. To address this problem, academic and private-sector leaders must recognise and manage biotechnology-related risks. In addition, strong biosafety procedures and an emergency reaction plan are essential.

In a circumstance where no one is advocating for the BMC's implementation, robust national legislation is essential. Both India and Pakistan have worked hard to develop solid legislation for their respective countries, but its implementation has not been as effective as it should be. For the creation of an effective plan, numerous reforms, additions, and adjustments are required. Both countries have ad hoc groups to oversee the recommendations' implementation. India has a more well-organized committee structure, with separate advising, review, and approval committees. If Pakistan had independent divisions like this, they could be more efficient in their implementation.

More attention is required by both the countries in cases of representation of researchers and academicians in policy making. There is not enough representation by both these sections in policy making. The countries even lack a law-based approach for biosafety[49]. There are no provisions for the victims of biohazards in their legislations[50]. It is imperative that victims and helpless persons who are affected by biohazards receive immediate care. There is a critical need for them to coordinate their actions with other relevant agencies such as the police, health, agriculture, and others who may play a role in the implementation of these laws. The provisions of the BWC should also be included into educational and training programmes, as well as research funding institution policies[51]. International Organisations play a very important role in solving the problem of Biosafety.

[49] *Supra* note 5 at 4.
[50] *Ibid.*
[51] *Supra* note 26 at 7.

Many organisations like African Biological Safety Association, British American Security Information Council and so on work on the problem of biosafety and therefore it can be suggested that both India and Pakistan need more International support and newer ideas from the global organisations. One of the organisations of which both the countries are a part of is SAARC (South Asian Association for Regional Cooperation) whose one of the objectives is to accelerate the social and the economic development of the countries. It can be one of the best mediums to attract the problem of biosafety in these countries. The members of SAARC also need more exposure and global understanding of best biosafety governance laws and regulations and therefore SAARC as a platform could help all the member nations to improve their biosafety standards and make it at par with the International standards.

V. Conclusion

Biosafety rules and regulations are the need of the hour. With Covid-19 pandemic being around the corner, the world has understood the importance of effective biosafety rules and what could be the consequences of a negligent behaviour towards the same[52]. Given its international commitments, India would have to examine the existing systems for ensuring that biotechnology does not have a negative influence on the environment. Apart from a lack of involvement and sluggish approvals, Indian regulatory organisations require political support and technical expertise in order to successfully implement and supervise GMO studies. Both India and Pakistan have been robust in their legislative framework for biosafety in their respective countries but they lack in its effective implementation. An effective legislative framework along with a strong law-based approach is a dire need for both the countries. The researcher believes that the incorporation of researchers in policy making along with a strong penalizing procedure for the violators and assistance for the victims would be a step towards an effective implementation.

A better infrastructure for educating and training people in the above stated laws will also prove to be effective in better biosafety governance. India and Pakistan need better and newer ideas followed globally which can be made possible by International Organisations. These organisations can help both the countries to frame better laws and better mechanisms to implement those laws. In conclusion, biosafety concerns necessitate effective policy and

[52] *Supra* note 4 at 2.

legislation governing the safe, secure, and responsible conduct of science, as well as capacity building to raise awareness and train researchers, all of which must be backed up by collaborative efforts among international governments, clinicians, veterinarians, agriculturists, ecologists, and scientists. Biosafety and biosecurity practises must be strengthened for global health and security, as failures can not only hurt people and the environment, but also cause economic impact.