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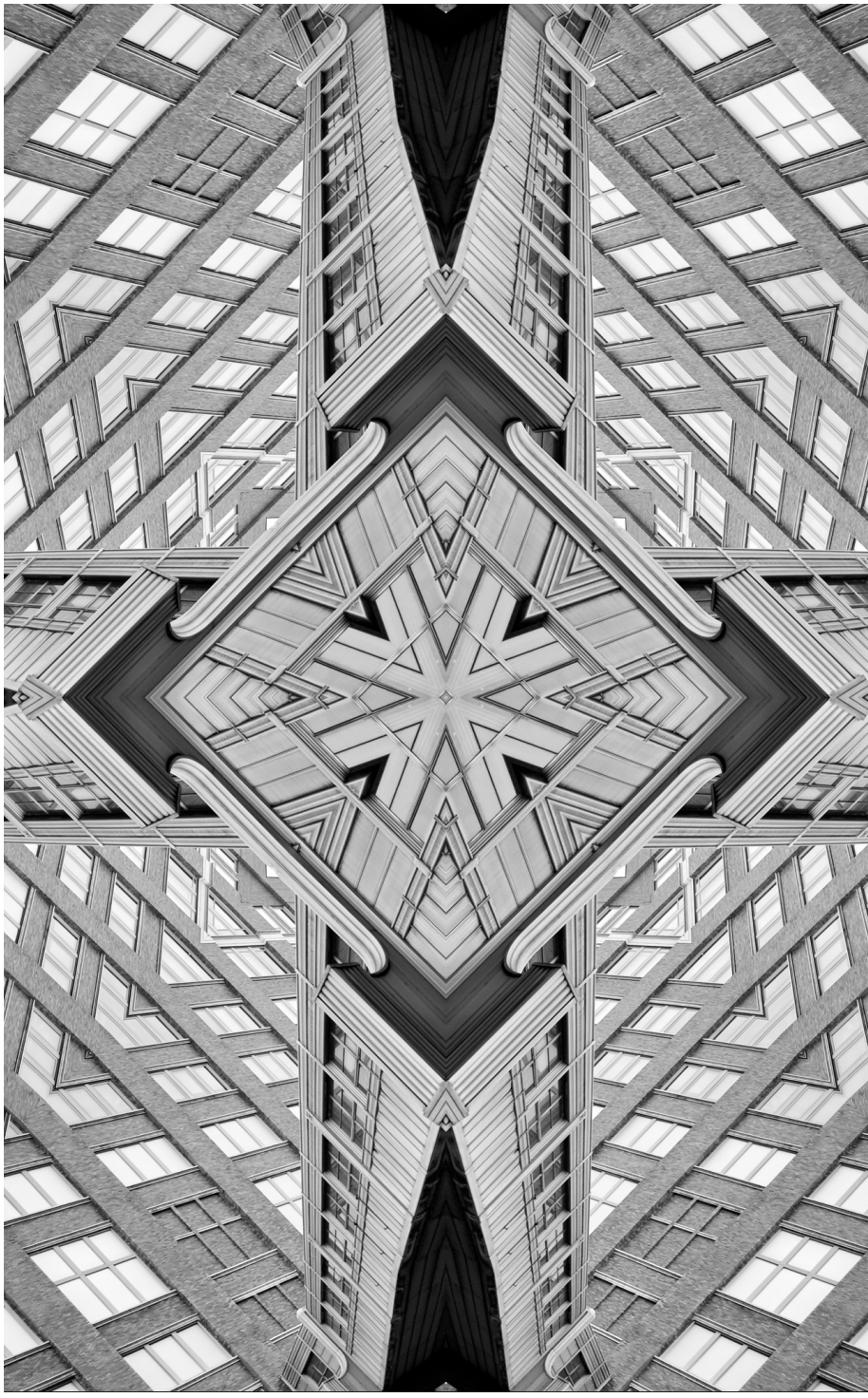

Laboratory Biosafety in India: In Search of a Sound Regulatory Framework

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Abstract

In the biomedical field, laboratories must ensure biosafety while managing pathogens and microorganisms in order to protect personnel and the broader community against potential leaks and lab-acquired infections. Global standards provide a roadmap for the biosafety of laboratories, underscoring the importance of their design and equipment, personnel training, waste management, and communication in preventing potential biohazards from breaching containment. In India, the government has established certain guidelines to address biosafety concerns. These evaluate and categorise the biosafety levels of laboratories to streamline the approach to risk management, with the Biotechnology Regulatory Authority of India Bill designed to serve as the primary legislation for modern biotechnology. This brief examines the significance of laboratory biosafety and analyses prevailing global standards. It also discusses existing gaps and challenges in India's guidelines.

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Introduction

Biosafety refers to the responsible use of biological materials and curbing the risk of leaks to protect human health and the ecosystem.[1] Biosafety level (BSL) laboratories are specialised facilities that need to follow precautions to ensure the safe handling of hazardous biological agents.[a,2] The laboratories are designed to provide a secure and enclosed containment setting, which includes primary protective barriers (safety equipment) and secondary protective barriers (safety facilities).[3]

BSL labs comprise four levels based on protection, design features, equipment, and standard practices.[4] These levels are subdivided into types based on their offerings.

Table 1: BSL Levels

Biosafety Level	BSL-1	BSL-2	BSL-3	BSL-4
Description	Basic laboratories that do not require special containment equipment.[5]	Basic laboratories that do not require special containment equipment.[6]	Laboratories designed to handle severe biological agents that are lethal for individuals but are low risk to communities.[7]	Highest containment level for handling hazardous biological agents that pose lethal risks to humans and the environment.[8]
	Usually work with well-known biological agents that pose little or manageable risk of causing disease in healthy adults or as environmental hazards.[9]	Typically work with well-known biological agents that pose little or manageable risk of causing disease in healthy adults or as environmental hazards.[10]	These biological agents' infections require expert intervention.[11]	These biological agents often have no preventive or therapeutic interventions.[12]

a Biological agents refer to any bacteria, virus, or toxin that can impact living organisms or the environment.

Biosafety Level	BSL-1	BSL-2	BSL-3	BSL-4
Description	Biological agents studied in BSL-1 include escherichia coli and K12 derivative.[13]	Biological agents studied in BSL-2 include salmonella and staphylococcus.[14]	Diseases studied here can include tuberculosis.[15]	Certain strains of retroviruses, including human immunodeficiency viruses (HIV) and simian immunodeficiency virus (SIV), are usually contained here.[16]
Sub-Types		Type-1: Laboratory for Risk Group (RG)-2 agent diagnosis.[17]	Type-1: Basic laboratory for diagnosis of RG-3 public health disease agents.[18]	Cabinet laboratories: All biological agents are placed in Class III Biosafety Cabinets;[b] the laboratories are also designed to prevent contamination. Suit laboratories: Require the staff to wear decontaminated full-body suits upon entry and exit.[19] Certain strains of lassa virus and marburg virus are maintained in BSL-4.[20]
		Type-2: Laboratory with facility for propagation of infectious RG-2 agents.[21]	Type-2: Laboratory with facility for propagation of infectious agents in vitro and in vivo for RG-2 agents and equipped for diagnosing extensively drug-resistant (XDR) and multi-drug resistant (MDR) tuberculosis (TB).[22]	

b Biosafety cabinets are a type of biocontainment. Most cabinets use high-efficiency particulate air (HEPA) filters in both the exhaust and supply systems to prevent exposure to biohazards.

Biosafety Level	BSL-1	BSL-2	BSL-3	BSL-4
Sub-Types		Type-3: Laboratory with facility for propagation of infectious agents in vitro and in vivo for RG-2 agents and equipped with providing diagnosis for XDR and MDR TB.[23]	Type-3: Laboratory for diagnosis with the mandate of in-vitro propagation of specific infectious agents for RG-2 related to DNA recombination technologies or RG-3, MDR, and XDR-TB agents.[24]	
			Type-4: Laboratory for diagnosis with the mandate of in-vitro and in-vivo propagation of specific infectious agents for RG-3 related to DNA recombination technologies or RG-3, MDR, and XDR-TB agents.[25]	
			Type-5: Laboratory for diagnosis with the mandate of in-vitro and in-vivo propagation of specific infectious agents for RG-3 related to DNA recombination technologies or RG-3, MDR, and XDR TB agents and with experimentation facility with RG-3 agents equipped with animal experimentation with RG-3 agents.[26]	

Source: Author's own, using various open sources.

The primary purpose of BSL laboratories is to study biological agents while protecting researchers and preventing the release of harmful pathogens into the environment. The safe and secure operation of these laboratories depends on reliable containment, well-trained personnel, knowledgeable supervisors, and adherence to biosafety manuals and standard operating practices.

In India, BSL laboratories are growing in number but remain fewer than those in countries of the Global North. There are 44 registered BSL-4 labs across the world, of which one-fourth are located in the United States (US).[27] India has one BSL-4 lab, established in 2019 by the ICMR on the premises of the Microbial Containment Complex (MCC), National Institute of Virology, Pune, with support from the Department of Science and Technology (DST).[28] India also hosts one BSL-3+ lab, in the National Institute of High-Security Animal Diseases (NIHSAD) in Bhopal, Madhya Pradesh.[29] The most common category in India is BSL-3, with eight such registered laboratories in the country.

The most frequent modes of infection transmission in lab-acquired infections (LAIs)[30] are inhalation, entry through the skin, direct contact with contaminated surfaces, and ingestion.[31] Globally, the most common viral LAIs are the hepatitis B virus, the hepatitis C virus, and the human immunodeficiency virus (HIV), while the most common bacterial LAIs are brucella, shigella, salmonella, tuberculosis, and meningitidis.[32]

There have only been two reported cases of LAIs in Indian BSL labs,[33,34] which may indicate a lack of trust in reporting mechanisms rather than the presence of good standards. While there have been some minor infections and leaks, the mechanisms in place for reporting such leaks are usually difficult, and staff and professionals often delay reporting out of fear of being reprimanded.[35] Additionally, in the case of LAIs, early symptoms are difficult to identify.[36] While LAIs and reported outbreaks involving hazardous RG-4[c] agents are uncommon, establishing biosafety guidelines is essential to fostering research around such agents.

c The World Health Organization has divided biological agents and toxins into risk groups, which will be discussed later in the brief.

Adequate training and education are essential for recognising and preventing outbreaks. The concerns around LAIs extend to public and community health, as an infected lab worker can transmit the infection to others. Thus, biosafety guidelines need to include standards that encourage communication and trust among personnel and staff who handle biological agents, and personnel need to be motivated to report anomalies without fearing recrimination.

Depending on the facility, the essential components of biosafety guidelines include conducting bio-risk assessments and identification; implementing specific biosafety measures; conducting medical surveillance; providing staff training; and ensuring safety measures for radiation, chemical, or biological agent leaks and infections.[37]

Global Networks and Associations

- The International Federation of Biosafety Associations (IFBA), formerly known as the International Biosafety Working Group, was created in 2001 to promote safe and secure handling of biological materials.[38]

- The American Biological Safety Association International (ABSA International), founded in 1984, caters to the growing needs of biosafety professionals in the US and engages with other associations worldwide.[39] Other regional associations, such as the European Biosafety Association (EBSA) and the Asia Pacific Biosafety Association (A-PBA), have also been established to represent countries in Europe and the Asia-Pacific regions, respectively. [40]

- The Global Health Security Agenda (GHSA), established in 2014, is based in the US and adopts a multisectoral, inter-agency governmental approach to address global infectious disease threats. In addition to focusing on biosafety and biosecurity[d] collaboration with partner countries, the GHSA aims to mitigate the impact of naturally occurring outbreaks and the accidental or deliberate release of dangerous pathogens.[41]

- The Global Virome Project (GVP), initiated in 2018 by experts from the US, China, Brazil, Italy, and Nigeria, aims to identify viral threats and provide timely and critical data support for public health interventions for future pandemics.[42,43]

d Biosecurity usually refers to using biological agents against a mass of people for political impact. The deliberate use of biological agents in terrorism and restrictions against them falls under biosecurity.

Global Standards and Guidelines

- **International Organization for Standardization**

Assessing the risks associated with biohazardous agents is crucial for determining the BSL of a laboratory. Consequently, the International Organization of Standardization (ISO) has outlined four umbrella steps: identifying hazards and risks; evaluating risks; implementing a risk mitigation plan; and evaluating the effectiveness of controls.[44] The US Centers for Disease Control and Prevention (CDC) has incorporated these guidelines towards biological risk management and governing BSL laboratories.[45]

The CDC's risk assessment focuses on the infectivity[e] and transmissibility[f] of hazards. The BSL is impacted by the work conducted and agents used in the laboratory. While the CDC oversees only US-based BSL labs, its influence extends to other parts of the world, especially those that engage in trade, global policy, and data sharing in medicine with the US.[46]

- **World Health Organization**

Since its establishment in 1948, the World Health Organization (WHO) has been developing surveillance networks for the monitoring and control of emerging and re-emerging infectious diseases. These networks include programmes initiated by WHO and collaborations with independent programmes like the Global Influenza Surveillance and Response System (GISRS) and the Global Infection Prevention and Control Network (GIPCN).[47] WHO also established the International Health Regulations, which provide guidelines for biosafety in order to prevent and restrict the impact of epidemics.[48]

WHO has also established a risk-group classification for hazardous agents used in biomedical settings, categorised on the basis of the route of natural disease transmission. There are four risk groups:[49]

- Risk Group 1: Negligible individual or community risk; treatments and preventive therapies commonly available. Example: A non-infectious rotavirus

e A pathogen's ability to establish an infection or its potential for horizontal transmission.
f The ease of transmission of a pathogen from one host to another.

- Risk Group 2: Mild to adequate individual risk, low community risk; treatments and preventive therapies commonly available. Example: A tickborne encephalitis virus

- Risk Group 3: Elevated individual risk, mild to adequate community risk; treatments and preventive therapies available through expert intervention. Example: Creutzfeldt-Jakob disease agent (prions)

- Risk Group 4: Extreme individual and community risk; no treatments or preventive therapies available. Example: The Creutzfeldt-Jakob disease agent (prions) is also applicable here, depending on the availability of cure and prevention methods. Here, the scope of new research and limited development also impacts risk levels.

While biosafety levels are consistent globally and based on WHO standards and global certifications, risk levels of infectious diseases may vary according to changing time periods and available local treatments. Additionally, the four risk-group classifications do not directly correspond to the BSLs implemented in a laboratory setting.[50]

The WHO Biosafety Manual also covers risk assessment, laboratory design and maintenance, biological safety cabinets, and other primary containment devices, protective suiting, decontamination and waste management, biosafety programme management, and outbreak preparedness and resilience.[51] The Food and Agriculture Organization (FAO) of the United Nations and the World Organisation for Animal Health (OIE) have also published similar biosafety manuals.[52]

- **Convention on Biological Diversity**

In 1992, the United Nations Conference on Environment and Development (UNCED) established the Convention on Biological Diversity (CBD), which is an international legal instrument between 192 ratified signatories. The CBD has two main protocols—the Nagoya Protocol and the Cartagena Protocol—and aims to conserve biological diversity through the sustainable use of its components and encourage equitable benefit sharing from research.[53]

Current Global Governance Mechanisms

- Cartagena Protocol

The Cartagena Protocol ensures "the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health, and specifically focusing on transboundary movements."[54] The protocol covers the gain of function research[g] and other forms of genetic modification.[h]

- Nagoya Protocol

The CBD established the Nagoya Protocol for "the fair and equitable sharing of the benefits arising from the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components."[55]

Both protocols highlight the importance of risk assessment, management, and compliance, as well as the regulation of the trade of biological agents, animals, plants, and food to lower risk and environmental impact. The protocols also recommend that state parties engage in bilateral and multilateral cooperation as well as collaboration among internal authorities to ensure sustainable biosafety and biological diversity.[56] The protocols serve as guidelines to form jurisdictional legislation, and their influence is evident in biosafety regulations worldwide, including in India.

g 'Gain of function' refers to a mutation that changes the molecular structure of a gene.

h Genetic modification can range from GMO foods (genetically modified objects), which dominate current agricultural outputs, to CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) editing, which can impact healthcare.

Indian Biosafety Guidelines and Regulations

India has been a signatory to the Cartagena Protocol on Biosafety since 2003 and the Nagoya Protocol since 2011 and often looks to these protocols for guidance on domestic biosafety.[57,58] The risk assessment guidelines and recommendations presented in the WHO Laboratory Biosafety Manual have also influenced India's approach to biosafety.

Biosafety labs in India are governed by various regulations and guidelines to ensure the safe handling and containment of hazardous biological agents, including pathogens and genetically modified organisms (GMOs). The primary regulatory authority overseeing biosafety labs in India is the Department of Biotechnology (DBT) under the Ministry of Science and Technology.[59]

Table 2 summarises the biosafety and BSL laboratory regulations and guidelines in India.

Table 2: Governing Instruments for Biosafety and BSL Laboratories in India

Governing Instrument	Relevant Functions
Emissions	
Air (Prevention and Control of Pollution) Act[60]	• The Air Act was enacted in 1981 and amended in 1987. The amendments focused on toxic emissions (including industrial) and introduced State Board powers to establish standards for emission and penalties against non-compliance. • The Central Pollution Control Board (CPCB) also implements the National Ambient Air Quality Monitoring Programme (NAMP) under this Act and releases standards and trends annually.[61] The programme highlights specific emissions to be monitored regularly, including sulphur oxide and nitrogen oxide.
Water (Prevention and Control of Pollution) Act[62]	• The Water Act was enacted in 1974 and amended in 1988. The amendments include industrial responsibility against pollutants and emissions into water bodies.
Solid Waste Management Rules, 2016[63]	• Enacted in 2016, these rules include pollutants that impact organic, inorganic, and chemical waste eliminated by local bodies.

Governing Instrument	Relevant Functions
Biotechnology and Biological Agents	
Rules for the Manufacture, Use, Import, Export, and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989 (1989 Rules)[64]	• These rules are the primary legislation addressing biosafety in India and fall under the Environment Protection Act of 1986.[65] • The rules were enacted to ensure the safe use of GMOs and related organisms to prevent potential risks to human health, animals, and the environment. They establish guidelines for various biosafety aspects, including the import, export, research, and commercial use of GMOs. However, since March 2022, the decision to grant permission to some classes of genetically edited crops (SDN 1 and SDN 2)[i] to enter the Indian market was criticised.[66,67]
Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008[68]	• The ICMR, the scientific and technical advisory body to the Ministry of Health and Family Welfare (MoHFW), has established guidelines on risk assessment, toxicity, and preparation for negative externalities for genetically engineered plants.
Guidelines and Standard Operating Procedures for Confined Field Trials of Regulated Genetically Engineered Plants, 2008[69]	• These guidelines summarise the information requirements and procedures under the 1989 Rules for evaluating and approving applications for confined field trials.
Protocols for Food and Feed Safety Assessment of Genetically Engineered Crops, 2008[70]	• The protocols were developed under the 1989 Rules to help assess the validity of genetically engineered crops and agents to be released into the environment.
Guidelines and Handbook for Institutional Biosafety Committees (IBSCs), 2011[71]	• The handbook outlines the structure and responsibilities of IBSCs and oversees research activities related to rDNA technology; transgenic plants; large-scale trials; and production, import, and transfer/shipment. It also covers reporting mechanisms in case of spills or leaks. • An updated handbook was released in 2020.[72]

i Site-Directed Nucleases (SDNs) are classes of gene editing. These are of three types; SDN-1 and SDN-2 do not introduce foreign DNA, whereas SDN-3 requires the introduction of foreign DNA.

Governing Instrument	Relevant Functions
Draft Manual for Biosafety in Public Health Laboratories, 2016[73]	• The manual has been released by the MoHFW under the Integrated Disease Surveillance Project. • The manual provides technical guidelines for public health laboratories. It also outlines best practices for clinical workers and lab workers and highlights different scenarios in biosafety labs, from leaks to infections. However, reporting mechanisms and risk assessments still need to be incentivised and encouraged to mitigate delayed reporting. It also briefly mentions bioterrorism without expanding into methods for identification.
Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India, 2016[74]	• These guidelines highlight prerequisites to pharmacology studies, including toxicity assessments and immune responses in animals and the Pharmacovigilance Plan and Adverse Drug Reaction (ADR) Reporting.
Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017[75]	• This set of guidelines outlines the operating standards for BSLs, animal BSLs, plant BSLs, aquatic organism BSLs, and insect BSLs. The guidelines address containment, laboratory monitoring and surveillance, decontamination and disposal, and emergency procedures.
General Guidelines for Establishment of BSL-3 Laboratory[76]	• Outlined by the ICMR, the guidelines cover the classification of biological agents by risk groups, practices to curb risk, and biological risk assessment for BSL-3 labs.
Biological Diversity Act, 2002[77]	• Inspired by the CBD, the Act ensures the conservation and sustainability of biological diversity and fair and equitable sharing of the benefits of using biological resources, research, and knowledge.
The Biotechnology Regulatory Authority of India (BRAI) Bill, 2013[78]	• The Bill established an autonomous entity known as the Biotechnology Regulatory Authority of India (BRAI) to oversee the research, transport, trade, containment, manufacture, environmental release, and use of organisms and products derived from modern biotechnology. • A Biotechnology Regulatory Appellate Tribunal will handle civil cases related to significant issues concerning modern biotechnology. This tribunal will also handle appeals regarding BRAI's decisions and orders.

Governing Instrument	Relevant Functions
Overseeing Authorities	
Recombinant DNA Advisory Committee (RDAC)[79]	• The RDAC reviews developments in biotechnology at the national and international levels and recommends suitable and appropriate safety regulations for India in recombinant research, use, and applications. • It is an advisory that functions from the DBT.
Institutional Biosafety Committee (IBSC)[80]	• The IBSC is established by an entity or individual, including research establishments, that deals with biological agents or GMOs in research spaces. The committee prepares an updated emergency strategy for on-site situations. • It is a regulatory body established to oversee processes and functions from the DBT.
Review Committee on Genetic Manipulation (RCGM)[81]	• The RCGM oversees safety-related aspects in ongoing research initiatives that involve GMOs or hazardous microorganisms. • The committee is responsible for creating guidebooks that outline the regulatory steps for activities involving genetically engineered organisms, both in research settings and applications such as industry, to ensure environmental security. • It is a regulatory body established to oversee processes and operates under the DBT.
Genetic Engineering Appraisal Committee (GEAC)[82]	• The GEAC is responsible for granting consent for activities that involve the application of biological agents in research and industry or the release of such agents into the environment. • The committee or its designated representatives are empowered to impose penalties as stipulated by the Environment (Protection) Act, 1986. • It is a regulatory body that oversees processes and works under the Ministry of Environment, Forestry and Climate Change.

Governing Instrument	Relevant Functions
State Biotechnology Coordination Committee (SBCC)[83]	• The SBCC conducts regular assessments of safety and regulatory protocols at different facilities that are engaged in manipulating GMOs or dangerous microorganisms. • The SBCC is authorised to conduct inspections and inquiries and enforce penalties in instances of legal breaches. These actions are carried out with the Nodal Department, State Pollution Control Board, or the Directorate of Health and Medical Services. • It is a monitoring authority at the state level.
District Level Committee (DLC)[84]	• The DLC enforces safety regulations at facilities that utilise biological agents and their environmental applications. It also creates an emergency plan for off-site field trials and addresses any potential emergencies. • It is a monitoring authority at the district level.

Source: Author's own, using various open sources.

Additionally, India's National Centre for Disease Control (NCDC) has laid out guidelines to address Zika virus, Nipah virus, and public healthcare association infections.[85] However, the biosafety regulations relating to research and innovation—the Draft Manual for Biosafety in Public Health Laboratories and the BRAI Bill—are yet to be formalised and passed.

Gaps in the BRAI Bill

The BRAI Bill aims to replace existing biosafety guidelines. However, since its release, it has provoked criticism due to apparent gaps.

- Need for clearer definitions: The Bill uses vague definitions, including of the term "substantial question relating to modern biotechnology". While the absence of a strict definition allows for flexibility, it may disrupt transparent governance.[86]

- Structure of the tribunal: The BRAI Bill highlights the need for a tribunal to oversee modern biotechnology processes in civil cases. The tribunal comprises one judicial member and five technical members. This

arrangement contradicts a Supreme Court ruling that technical members cannot outnumber judicial members on a tribunal bench.[87]

- Lowered standards for risk assessment and lowered penalties: The BRAI Bill does not mention risk assessment methods. Further, it lowers standards for existing risk assessment by not prioritising regular risk assessments that may prevent LAIs. If the Bill aims to replace other regulatory tools, it cannot reduce requirements that are already lax according to global standards. Additionally, per its other clauses, all biotechnology trade is considered as exchanging trade secrets, and penalties amount to an insignificant level for industry (i.e., up to four years' punishment or INR 5 lakhs penalty).[88] Assessment and redressal methods need to be re-established in greater detail by focusing on the impact of existing laws.[89]

The Indian biosafety regulatory ecosystem is a well-formed web; however, it lacks a central regulation that can govern biosafety, labs, and reporting mechanisms as well as ensure compliance. The BRAI Bill aims to become an umbrella authority in modern biotechnology and biosafety but there are concerns around its validity. The Bill was introduced in parliament in 2013 and was referred to a standing committee. However, after the parliament dissolved the session, the BRAI Bill lapsed[90] and has not been introduced. If the BRAI Bill aims to become the primary legislation in the biotechnology sector, with the Biotechnology Regulatory Authority Tribunal (BRAT) as the primary authority, addressing the gaps needs to be prioritised.

Development of Standard Practices

The introduction of the BRAI Bill reflects a desire to standardise policies in the Indian biosafety landscape. However, if the Bill is to become a suitable replacement for existing biosafety standards, it needs to address the ambiguity in definitions and incorporate more specific operational and definitional standards. The DBT will need to realign the BRAI by developing a consensus for standards and strategies amongst all players, from farmers to large corporations, to ensure greater consistency and compliance. The system adopted by the DLCs and SBCCs can be replicated to ensure representative participation while developing these definitions.

First, the Bill must address definitions of 'modern biotechnology'; extract existing definitions of biotechnology, including genetic modification and the function of research; and align these definitions with existing national and international regulations and guidelines. Operationally, the Bill will need to enforce more severe penalties in case of industry lapses, including heavier fees for non-compliance.

Second, the internal structure of the BRAT needs to ensure the appropriate representation of technical and judicial experts in alignment with Supreme Court rulings. The number of technical and judicial experts needs to be balanced while allowing for global policy experts. The tribunal's structure can also replicate those of the DLCs and SBCCs, which allow for different levels of monitoring and regulation to oversee the processes in BSL labs. Such a tiered structure under the same legislation will ensure that cases are addressed without bottlenecks.

Risk Assessments and Reporting Mechanisms

As in the case of the COVID-19 pandemic, biosafety labs may need to work on rapid timelines while ensuring safety. This trend is bound to be amplified with emerging biotechnology and nanotechnology.[91]

The diverse range of laboratory activities, including routine clinical testing and unique research, necessitates site- and procedure-specific risk assessments. There is a need for additional data collection on current and future risks and applied research to guide the development and implementation of biosafety guidelines and best practices. Current biosafety recommendations often rely on

opinion or perceived risk due to limited documented infections, and there is a need for available data and best practices research to be updated.[92] Current and future versions of the BRAI Bill need to prioritise updating procedures and conducting new risk assessments.[93]

While LAIs may still occur despite regular risk assessments, they can be limited through personnel training and responsibility. Researchers must establish learnings from past cases and lapses in reporting and risk assessment to anticipate future leaks, spills, or LAIs. Additionally, to curb non-reporting or delayed reporting of LAIs, workers should be encouraged to use existing reporting methods without the threat of dismissal. These reporting methods should be easily accessible, anonymous, and non-punitive in order to mitigate leaks in the nascent stages and assist regulatory authorities in mapping leaks, spills, and LAIs globally. Regular seminars on reporting methods can also be conducted for the staff.

Compliance Measures

Biosafety regulations are only effective when coupled with consistent enforcement measures and penalties for wilful non-compliance by commercial authorities. One such case was noted in 2001 when Navbharat Seed Pvt. Ltd., headquartered in Ahmedabad, Gujarat, formulated a hybrid Bt cotton variant, NB-151.[94] Despite gaining approval from Gujarat's variety registration system as a bollworm-resistant cotton hybrid, NB-151 did not seek approval from New Delhi's biosafety regulatory authorities.[95] The issue came to light in 2001, after most of the cotton in Gujarat suffered bollworm damage.[j] Despite ongoing efforts by the GEAC to encourage crackdowns on the spread of unapproved Bt varieties, there has been limited action from Gujarat and other states.[96]

A BRAI Bill and a BRAT-like authority are necessary to prevent such cases. However, the current versions of these guidelines need to be enhanced to incorporate multi-level cooperation and introduce penalty systems and legal guarantees to ensure compliance from the industry and recall in case of non-compliance.

j A larva infestation that affects cotton plants.

International Collaborations

Lower- and Middle-Income Countries (LMICs) offer safe environments based on existing Global North standards, allowing foreign experts to work autonomously.[97] However, Global North BSL labs are more trusted despite ethical concerns such as benefit sharing; equitable access to research outcomes; use of data for local concerns in research collaboration; citing the lower level of occupational safety and health in LMICs.[98] In much of the Global South, mobile labs are part of local public health responses;[99] India announced its first mobile biosafety lab in February 2002.[100] Mobile labs have distinct rules for managing occupational safety and health and defining local and foreign experts' roles in responding to public health requirements. Funding collaborations, especially with international collaborations, can ensure responsible research with globally aligned goals.

There are various global governance and collaboration standards that encourage biosafety and standardise procedures. India has a well-structured set of regulations for biobanking and sharing research and profit benefits.[101] In order to enhance its biosafety industry, India needs to establish an authority that engages with current international collaborative measures and encourages future collaborations on harmonised standards and research. BRAT can function as such an authority, provided the BRAI Bill incorporates the above recommendations and is passed.

Conclusion

BSL laboratories play a role in safeguarding public health and the environment by providing controlled environments for studying biological agents. While lab-acquired infections are rare, there is a need for safety guidelines to limit these potential occurrences. International organisations such as the International Federation of Biosafety Associations and the Asia Pacific Biosafety Association work to promote biosafety standards and collaboration worldwide. In India, domestic biotechnology and biosafety are regulated by the DBT and the NCDC. Additionally, India needs to establish nodal legislation and agencies for interacting with global biosafety organisations and encourage international cooperation under the Ministry of External Affairs of the Ministry of Science and Technology.

For India to incorporate a regulation like the BRAI and an authority like BRAT, there is a need to improve biosafety standards in the country to create a functional ecosystem and establish global standards. This can be achieved by strengthening risk assessment methods, improving reporting mechanisms for potential hazards, developing standardised practices for different types of laboratories, enhancing routine risk assessments, fostering international collaborations, and implementing robust compliance measures with clear penalties for non-compliance.

The collective efforts of governments, international organisations, researchers, and regulators are vital to ensuring the safe handling of biological agents, preventing outbreaks, and maintaining global health security. Biosafety remains an evolving field that requires vigilance, cooperation, and adaptability to address emerging challenges and mitigate potential risks.

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Annex

Hosting Institutes for BSL-3 and BSL-4 Labs in India

Hosting Institute	City	Lab Biosafety Level
National Institute of Virology.[102]	Pune	BSL-4
National Institute of High-Security Animal Diseases.[103]	Bhopal	BSL-3+
Indian Council of Medical Research.[104]	Nashik	BSL-3
CSIR-Indian Institute of Integrative Medicine.[105]	Srinagar	BSL-3
Jawaharlal Nehru University.[106]	New Delhi	BSL-3
Delhi University.[107]	New Delhi	BSL-3
National Institute of Cholera and Enteric Diseases.[108]	Kolkata	BSL-3
Autonomous State Medical College.[109]	Shahjahanpur	BSL-3
All India Institute of Medical Sciences Patna.[110]	Patna	BSL-3
Indian Institute of Science (IISc).[111]	Bangalore	BSL-3

Source: Author's own, using various open sources

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