

A Proposal for Biosecurity Framework in India

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Summary

Perpetual biological threats in India presented in different forms, and of various intensities call for a comprehensive biosecurity framework. Rapidly advancing scientific developments in synthetic biology have altered the landscape of probable biological threats. Taking cues from legal biosecurity frameworks of developed nations; legally binding regulations along with integrated and wide-ranging biosafety, biosecurity and biodefense policies need to be re-designed to form the backbone of this robust comprehensive biosecurity framework.

Introduction

The biological threats in various forms and degrees of severity have been knocking on the door at a disturbing regularity. Fast-paced changes in interdisciplinary scientific advancements and geopolitical paradigms have been key to an equally fast-paced metamorphosis of the biosecurity landscape. The biosecurity preparedness domain in India is awaiting a complete overhaul in the approach; progressive, if not revolutionary!

The word plague is synonymous with tremendous morbidity, mortality, fear of unknown, psychological, psycho-social and economic impact. Though the Surat plague in 1994 was endemic, there is a distinct similarity between that plague and COVID-19 on several parameters. Some of them are mass testing and hospitalizations of suspected cases, massive scales of sanitary measures, national and international media coverage, travel restrictions, tourism and export bans resulting in economic impact. Another distinct similarity relates to the outbreaks giving rise to some unanswered questions such as the nature of the disease, mode of transmission, the origin of the outbreak, whether it was natural or man-made.¹

Irrespective of the origin of an outbreak of such nature and scale, the nation should be prepared to tackle the challenge swiftly. In this context, biosecurity preparedness comprises surveillance, detection, prevention, response and mitigation. Another important backbone of biosecurity preparedness is the legal framework to support various components of the biosecurity landscape.

Biosecurity

Biosecurity is a collective responsibility of the society to create a 'Web of Prevention' to protect populations, plants, animals and the environment against all biological threats and risks; whether incidental, accidental, intentional or experimental in nature and presented by biological agents, toxins and vectors.

As it was evident during COVID-19, the complexities of biological threats demand an equally complex collaborative and interdisciplinary 'Biosecurity Web of Prevention' that involves multiple agencies and countermeasures.

Biosecurity Landscape

The concept of Biosecurity and the regulations are distinctly different and empower different ministries or agencies that are responsible for sectors associated with public health, food safety, forests, agriculture, livestock, and the environment. Often, the terms 'Biosafety' and 'Biosecurity' are used interchangeably. However, broadly biosafety is to do with safety protocols, standard operating procedures (SOPs), safety related infrastructure and waste disposal, whereas biosecurity has many dimensions. The biosecurity perspective may be distinctly different for different stakeholders, even within the science and technology domain. The biosecurity landscape comprises of:

- Accidental lab leak, accidental spillage of biological agents or related information
- Theft, sabotage or weaponization of biological agents
- Gain of function research and dual-use research of concern (DURC)
- Foreign invasive species & agriterrorism

- Genetically Modified Crops, weeds and field testing
- Deliberately released infectious or toxic biological agents
- Food security
- Animal biosecurity, import, quarantine breeding and diseases
- Synthetic infectious agents built using freely available genomic knowledge on the internet and readily available building blocks
- Pests, vector-borne diseases, genetically modified and intentionally released insect vectors
- Zoonotic spill-over of diseases

The length and breadth of the biosecurity landscape need to be covered under a robust legal framework comprising of new legal provisions, some existing laws with necessary amendments, revival and required modifications in some draft bills presented in the past. This framework would facilitate the management of all biological threats whether public health challenges and emergencies, biosafety, biosecurity or biodefence needs of the nation.

Biosecurity Governance

The American biosecurity framework is an exemplary case. Since the American anthrax incident after the 9/11 attacks, various measures have been undertaken to implement and improvise the administrative aspects of biosecurity and biodefence. Multiple laws, statutes, regulations, directives, and government directives aimed at countering the biological threats are in force. These legally binding regulations form the critical backbone of the biosecurity web

of prevention. Some of the critical legal provisions include²:

- The Biological Weapons Anti-Terrorism Act of 1989
- Public Law 107–188, Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- Presidential Directives
 - HSPD 4: National Strategy to Combat Weapons of Mass Destruction (WMD): The strategy contains three principal pillars:
 - Counter-proliferation to combat WMD use,
 - Strengthened non-proliferation to combat WMDs,
 - Proliferation consequence management to respond to WMD use.
 - HSPD 9: Defence of United States Agriculture and Food
 - HSPD 10: Biodefense for the 21st Century
 - A comprehensive framework for biodefense,
 - The creation of the National Biodefense Analysis and Countermeasure Centre,
 - Increased funding for
 - New vaccines,
 - Intelligence initiatives,
 - Bio-surveillance,
 - Mass casualty care.

➤ HSPD 18: Medical Countermeasures Against Weapons of Mass Destruction

➤ HSPD 21. Public Health and Medical Preparedness

- Preparedness for all potential catastrophic health events;
- Coordination across levels of government, jurisdictions, and disciplines;
- Regional approaches to health preparedness;
- Engagement of the private sector, academia, and other non-government entities in preparedness and response efforts; and
- Delineate the important roles of individuals, families, and communities.

➤ National Biodefense Strategy 2018

These legally binding regulations along with integrated and wide-ranging biosafety, biosecurity and biodefense policies form the backbone of the robust comprehensive biosecurity framework in the US.

Similarly, Biosafety Strategy 2018 of the UK, Federal Law of Biological Safety, 2020 of Russia and Biosecurity Law, 2019 of China along with related biosecurity governance frameworks of these nations will be helpful to design and improvise Indian Biosecurity frameworks.

Legal provisions in India

During the early stage of COVID-19 pandemic, Epidemic Act 1897 and Disaster Management Act 2005 were invoked for the management of the outbreak.

Epidemic Diseases Act (ED1897)

Despite the criticism of it being an outdated law, this is the only law that has provisions to deal with such a situation specifically. The act emphasises on the states to manage public health crises while giving only ancillary powers to the centre. The 122-year-old law has many limitations with respect to the scope, limited and age-old surveillance, containment and quarantine methods or it does not specify the power structure in case of a dispute. Acknowledging this, Public Health Bill 2017 was drafted to repeal the Epidemic Diseases act (1897).

Disaster Management Act (DM2005)

While declaring the COVID-19 pandemic ‘a notified disaster’, the centre enforced the provisions of the DM2005. Though the DM act is not aimed at targeting epidemic disasters specifically and envisaged primarily for tackling natural disasters, the centre used another entry in the list to utilize the Act; ‘social security and social insurance; employment and unemployment’. The DM Act has provisions for both centre and the states to share power and responsibilities. Though public health is primarily listed under the State’s List, which is a caveat. This provision does not impede the centre from enacting a public health legislation related to outbreaks of epidemic proportions. There is a provision in entry 29 of the Concurrent List for the purpose of ‘prevention of the extension from one state to another of infectious or contagious diseases or pests affecting men, animals or plants’³.

Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism and Disasters) Bill 2017

Considering the limitations of age-old ED1897 and the need to empower the

government to effectively manage any health emergencies, the Public Health Bill 2017 was drafted by the National Centre for Disease Control (NCDC) and the Directorate General of Health Services (DGHS).

Challenges in the implementation of and comments on the Public Health Bill 2017:

- All the powers of the government at each level are clearly mentioned, but possible violations of rights during public health emergencies have not been taken into account and its redressal mechanisms are not clearly defined. An appeal can be made under this act, but still, the scope to appeal is very limited in the context of Sections 9 and 10.⁴
- Maintaining a balance between the rights provided by the constitution and the powers of the government is essential for the public health law. Contact tracing of affected individuals as a response to pandemic may violate the Right to Privacy in absence of any legislative provision as such. However, as public health is of paramount importance, privacy and public interest will be balanced once brought under the rigour of the law.⁵
- There is a need for a dedicated public health cadre to implement a Public Health Bill effectively.
- With easy access to the internet misinformation and disinformation campaigns can cause fear and panic among the people. The addition of penalties to prevent such activities should be considered. Provision of payment of compensation to the people affected by the government orders during an epidemic may be considered.
- During the COVID-19 outbreak several significant unresolved issues emerged. A

structured legal framework controlling mismanagement, malpractices, the lapse in providing basic medical aid, availability and distribution of medical essential drugs and equipment, is necessary.

- There needs to be a balance between the government's role in maintaining public health and human rights.⁶
- Though the Constitution does not directly have provisions for public health emergencies like the current pandemic, according to Article 246 of the Constitution, matters related to public order and health are mentioned in the state list. However, once central legislation becomes applicable, that is, Article 256. This provision says that states must comply with central laws, and the Centre can issue directions to demand compliance. The draft Bill mentioned the role and responsibilities of the Centre and states in a medical emergency.⁷

The Epidemic Diseases (Amendment) Bill 2020 has limited scope and is temporarily available. This legislative provides safeguards for healthcare workers need to be included in the new Public Health Bill with stringent penalties in respect of the duration of imprisonment and penalty amount etc.

The limitations of both ED1897 and Public Health Bill 2017 highlighted during the current pandemic can be overcome by drafting a new Public Health and Biosecurity Bill to make legal provisions for future health emergencies.

An important feature of The Public Health Bill 2017 is the inclusion of Schedule 1 (Epidemic Prone Diseases) and Schedule 2 (Potential Bioterrorism Agents). Both these schedules should be revisited and included

while drafting a new Public Health and Biosecurity Bill.

There is also a need to scrutinize some other relevant Acts and Bills with respect to Biosecurity, such as:

- Livestock Importation Act 2001
- Plant Quarantine Regulatory Act
- Customs Act 1962
- WMD & their delivery systems Act 2005
- Water & Air (Prevention and control of pollution) Acts
- National Security Act 1980
- Biotechnology Regulatory Authority of India Bill (BRAI2013) and Agricultural Biosecurity Authority of India Bill (ABAI2013)

A comprehensive Biosecurity framework calls for a fresh Biosecurity perspective to assess the legal provisions accorded by all above-mentioned laws and bills proposed earlier. Some amendments may be necessary to empower respective government dispensations for effectively managing their Biosecurity situations.

There is a need for a legal provision for a central mechanism with a team of epidemiologists, public health experts, policymakers, public health engineers to be in place to decide and declare diseases as public health emergencies based on International Health Regulations.⁸ Taking cues from BRAI2013, another legal provision calls for a Regulatory and Emergency Committee to examine unexpected outbreaks; also being responsible for strengthening national disease surveillance, prevention, control and response systems and responses at the international level.⁹

The proposed Biosecurity Framework would ideally comprise of:

- Relevant structured legal provisions with power structure at all levels with clearly defined roles and responsibilities at all levels of governance;
- SOPs, penalties and redressal mechanisms for all relevant situations and health emergencies;
- Healthcare Emergency management should be inclusive of logistics of essential medical supplies and equipment and emergency authorizations.

Taking cues from legal biosecurity frameworks of developed nations; legally binding regulations along with integrated and wide-ranging biosafety, biosecurity and biodefense policies need to be re-designed to form the backbone of this robust comprehensive biosecurity framework.

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