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THE REGULATION OF IMPERATIVE OF GLOBAL BIOSECURITY: ANALYZING BIOLOGICAL WEAPONS

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Abstract:

The specter of biological warfare persists as a crucial concern in the 21st century. This analysis explores the complex domains of international legal frameworks, biomedicine and bioweapons. It examines the historical evolution of efforts to control and prevent the use of biological agents in warfare, beginning with landmark agreements like the Biological Weapons Convention (BWC) of 1972.

This research highlights the inherent tension between the beneficial applications of bio-inventions and the potential misuse in developing deadliest weapons. This exploration underscores the urgency of navigating the ethical dilemmas and global governance challenges posed by advancements in biotechnology.

Key principles and Frameworks – A Multifaceted Approach: the international community's response to bioweapons threat involves a diverse array of actors and mechanisms. Organizations such as the World Health Organization (WHO), and the United Nations Office for Disarmament Affairs (UNODA) play crucial roles in monitoring, enforcing and promoting compliance with existing legal frameworks. Several countries undergone to the bilateral treaties to control use of bioweapons. The National Biosecurity Working Group (NBWG) and initiatives like the "One Health" approach emphasize the importance of a coordinated, multi-sectoral response.

The landscape of biosecurity is constantly evolving, shaped by technological advancements and emerging threats. The rise of bioterrorism, the potential misuse of dual-use research and the increasing accessibility of advanced biotechnologies present significant challenges. The emergence of biological weapons, biotechnology innovation, and the dilemmas associated with bio-labs necessitate continuous adaptation of legal and policy frameworks. The potential role

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of artificial intelligence (AI) in warfare further complicates the issue. The need to address the "misuse" and "malicious" aspects of bioweapons capabilities, along with the "dilemmas" they create, is paramount.

This analysis underscores the importance of strengthening national and international biosecurity measures to prevent the development and deployment of biological weapons, ensuring a future where scientific progress serves humanity rather than endangering it. Fostering a future where the promise of biotechnology is realized without the looming shadow of biological warfare.

In conclusion, this analysis reveals that effective global biosecurity necessitates a proactive and adaptive approach. It demands a commitment to strengthening national and international measures, fostering responsible innovation, and promoting ethical vigilance. By bridging the gap between scientific progress and security, and through robust international cooperation, we can ensure that biotechnology serves as a force for good, safeguarding humanity from the devastating potential of biological warfare. Fostering a future where the promise of biotechnology is realized without the looming shadow of biological warfare remains our collective imperative.

Keywords: Biological Weapons, Biosecurity, International Legal Frameworks, Global Governance

Introduction:

In recent years, advances in science & technology have made it easier & cheaper to produce biological agents which could be developed into BWs[1]. Constantly, understanding the nature of these threats and establishing effective countermeasures are paramount for safeguarding public health and national security in the 21st century. Given the rapidly evolving technology which has made these weapons both accessible and affordable, the importance of preparedness of a well-equipped public health system can hardly be overestimated[2].

[1] Rajagopalan Vijayaraghavan, "Biological Warfare Agents," Journal of Pharmacy & Bioallied Sciences, 2, no. 3 (2010).
[2] Article: - Devi Kalyan Mishra - Bioterrorism from a Public Health perspective.

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What is Bioweapons (BW)?

The World Health Organization (WHO) defines a biological weapon (BW) as micro-organisms like virus, bacteria, fungi, or other toxins that are produced & released deliberately to cause disease & death in humans, animals or plants.[3] This definition highlights the intentional use of biological agents with the specific aim of inflicting harm, distinguishing it from naturally occurring disease outbreaks. Any number of biological agents can be utilized as BWs & are typically divided into three categories; Bacteria such as anthrax; Viruses such as Ebola & Smallpox; toxins such as botulinum & ricin.[4] The categorization of these agents based on their potential for harm is crucial for developing appropriate response strategies and allocating resources effectively.

What is Bioterrorism?

Bioterrorism can be defined as the deliberate release of viruses, bacteria, toxins or other harmful agents used to cause illness or death in people[5]. This act of intentional release distinguishes bioterrorism from other forms of biological threats, emphasizing the malicious intent behind it to create fear and disruption. Centers for Disease Control & Prevention (CDC) plays an important role in helping to establish, maintain and expand the Surveillance. This work is conducted through the World Health Organization's Global Influenza Surveillance & Response System (GISRS)[6]. Such collaborative international efforts are vital for early detection, risk assessment and coordinated responses to potential global health threats, including those posed by biological agents.

The Intersection of Bio innovation, Biotechnology and Bioweapon

The remarkable advancements in biotechnology hold immense promise for addressing global health challenges and driving innovations across various sectors. However, the very knowledge and techniques that fuel these "bio-inventions" also present a potential duality. This intersection, where the power of biological manipulation could be intentionally misused, raises critical concerns about biosecurity and the development of bioweapons. Exploring this nexus of innovation and potential peril is crucial for establishing robust regulatory frameworks and ensuring the responsible development and application based biotechnology "Biological

[3]World Health Organization, Biological Weapons: 2020 https://www.who.int/westernpacific/health-topics/biological-weapons. (Duraipandian Thavaselvam, 2023
[4] Reuben Ananthan Santhana Dass, Bioterrorism: Lessons from the COVID-19 Pandemic.
[5] Id.
[6] Centers for Disease Control & Prevention (CDC). Bioterrorism Overview 2008.

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Invention" is the intellectual work product of the industrial microbiologist, the plant breeder and the animal husbandman. The stale, or attenuated, cultures were called Vaccines; from the Latin word 'Vacca cow' (The first vaccination was Jenner's use of the cowpox virus in 1798 to prevent smallpox.)[7] According to this definition, we find grounding in practical, often agricultural origins. The mention of the "industrial microbiologist, the plant breeder and the animal husbandman" evokes a sense of traditional craftsmanship applied to biological processes. The term 'stale, or attenuated, cultures' for early vaccines highlights the empirical nature of early discoveries, a far cry from the sophisticated molecular biology of today. The etymological link to "Vacca cow" and Jenner's smallpox vaccine underscores the historical impact such inventions on human health, a legacy that continues to shape our understanding and pursuit of biological solutions.

This historical context servers as a reminder that even the most advanced biotechnologies have roots in more rudimentary, yet profoundly impactful, observations and manipulations of the natural world. It also implicitly suggests a trajectory of increasing complexity and power in our ability to harness biological processes.

Attempts to provide a regulatory mechanism for biotechnology in India started about 30 years ago with the introduction of the "Rules for the Manufacture, Use, Import, Export & Storage of Hazardous Micro-Organisms / Genetically Engineered Organisms or Cells by the Government of India in 1989."[8]

This research aims to suggest a growing awareness and policy response coinciding with the increasing capabilities within biotechnology. This early regulatory intervention lays the groundwork for the more comprehensive guidelines mentioned in the following research which highlighting a continuous efforts to balance innovation with responsible oversight.

Since then, a number of guidelines, rules, regulations & notifications have been instituted to ensure environmental safety in the use of genetically modified organisms (GMOs); provide regulatory approvals for dealing with genetically engineered (GE) entities; Promote research in Biotechnology, including the provision of patent rights on novel biotechnology innovation;

[7] Iver P. Cooper, Volume 1, Biotechnology and the Law Thomson Reuters, south Asian edition, New Delhi, 2014.
[8] Sreenivasulu N.S., Law Relating to Biotechnology. Age Oxford University Press, New Delhi, 2018.

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Protect & maintain Biological Diversity[9]. Furthermore, the mention of promoting "research in the field of Biotechnology which including the provision of patent rights on novel biotechnology innovation" reveals dual objective firstly, fostering scientific advancement while also establishing intellectual property rights frameworks. Finally, the directives of protection and maintenance of biodiversity adds another crucial layer, recognizing the potential for biotechnology to both benefit and potentially threaten the natural world, thus necessitating conservation efforts alongside innovation.

The extraordinary complexity of the changing human organism over the life course is one of the reasons why the near future biomarker research may be a period of more dark than light. Many scientists doubt that bio prediction of bad behaviours can or should have translational impact in the near future. However, new techniques bring new possibilities[10]. Some non-medical classifications of 'Bad Behavior' such as 'criminality' and 'violence' are freed of these particular accusations[11]. This statement about the 'extraordinary complexity of the changing human organism over the life course' is presented a reason why "near future biomarker research may be a period of more dark' this intriguing statement suggests that the intricate and dynamic nature of human biology might make the immediate future of biomarker discovery challenging and potentially fraught with uncertainties or misleading results. The phrase "more dark than light" implies a period of difficulty in interpretation, potential for false positives or negatives, or perhaps even ethical dilemmas arising from the information gleaned. This research highlights a reminder that while biotechnology offers powerful tools for understanding and manipulating life, the inherent complexity of biological systems can present significant hurdles and unforeseen consequences in their application, particularly in the realm of human health.

The "One Health" Approach:

The term 'One Health' was first used in 2003-2004, and was associated with the emergence of severe acute respiratory disease (SARS) in early 2003 and subsequently by the spread of highly pathogenic avian influenza H5N1, and by the series of strategic goals known as the 'Manhattan Principles' derived at a meeting of the Wildlife Conservation Society in 2004, which clearly recognized the link between human and animal health and the threat that diseases pose to food

[9] Supra note 7
[10] Ilina singh, Walter P. Sinnott-Armstrong, Julian Savulescu, Bioprediction, Biomarkers and Bad Behavior, Scientific-legal and Ethical Challenges, Oxford series in Neuroscience, Oxford University Press, 2014
[11] Supra Note 10

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supplies and economies. These principles were a vital step in recognizing the critical importance of collaborative, cross-disciplinary approaches for responding to emerging and resurging diseases and in particular, for the inclusion of wildlife health as an essential component of global disease prevention, surveillance, control and mitigation[12]. One Health is an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes that the health of humans, domestic and wild animals, plants and the wider environment (including ecosystems) are closely linked and interdependent. While health, food, water, energy and environment are all wider topics with sector-specific concerns, the collaboration across sectors and disciplines contributes to protect health, address health challenges such as the emergence of infectious diseases, antimicrobial resistance and food safety and promote the health and integrity of our ecosystem. By linking humans, animals and the environment, One health can help to address the full spectrum of disease control-from prevention to detection, preparedness, response and management and contribute to global health security. The approach can be applied at the community, subnational, national, regional and global levels and relies on shared and effective governance, communication, collaboration and coordination. Having the One Health approach in place makes it easier for people to better understand the co-benefits, risks, trade-offs and opportunities to advance equitable and holistic solutions[13].

COVID – 19 Pandemic: Bioweapon and Biosecurity:

The initial emergence of COVID-19 in Wuhan, China, in January 2020, at the Seafood Market, is widely considered the point of zoonotic spillover to humans. This novel virus rapidly propagated globally, resulting in a pandemic characterized by significant morbidity and mortality. Investigations in the precise origins and transmission mechanisms are ongoing. The global health crisis necessitated unprecedented scientific efforts, including vaccine development and clinical tails, raising critical bioethical considerations concerning resource allocation, equitable access and research integrity. The pandemic underscores the imperative for international collaboration and robust public health infrastructure to address emerging infectious diseases.

It is a huge bio medical issue which causing over 6 million global deaths, spurred intensive international scientific collaboration among researcher in the USA, China and India, leading to

[12] Pmc.ncbi.nlm.nih.gov/articles/PMC6630404/
[13] Who.int/health-topics/one-health#tab=tab_1

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diagnostic advancements and life-saving vaccines. Healthcare professionals faced the ethical imperative of beneficence and non-maleficence while investigating misinformation and patient confidentiality. India's rapid development of BBV152 (Covaxin) exemplifies scientific dedication. Notably, female scientists actively contributed to research efforts, highlighting the absence of gender discrimination within the healthcare profession. India's extensive vaccination drive, administering over 2.2 billion doses, demonstrates the application of beneficence and justice through infrastructure expansion ensuring equitable access to medical resources.

Preclinical vaccine trails involve in vitro and in vivo studies, typically utilizing animal model such as mice and monkeys, to assess safety prior to human testing. Regulatory approval, including permissions from relevant authorities like forest commissions for non-human trials, is mandatory ethical research practices necessitate informed consent for human subjects and adherence to established medical and research protocols. Scientific integrity demands transparent communication of research findings, including potential consequences and challenges encountered during vaccine development. Truth-telling, underpinned by trust and confidentially, constitutes a fundamental principle of medical ethics.

International Regulatory Legal framework and Human Rights

In the shadowy realm of future warfare, the absence of strong, universally accepted BWC protocols casts a long and ominous shadow. Without robust verification and enforcement mechanisms, the temptation to secretly develop and deploy biological weapons, the "dark side" of warfare, could escalate dramatically. Imagine a future where advancements in biotechnology, unchecked by stringent international oversight, lead to the creation of novel, highly contagious, and weaponized pathogens. These could be deployed covertly, blurring the lines of attribution and causing mass casualties and societal collapse with terrifying speed.

In some countries, law enforcement officials together with the members of the public health services conduct drills not only to educate their citizens about the possibility of bio-terror attacks but also to prepare the public as first responders in case an attack takes place (Ministry of Defense 2016).[14]

[14] Article: - Devi Kalyan Mishra - Bioterrorism from a Public Health perspective

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The lack of protocols also hinders effective response and accountability. Identifying the perpetrator of a biological attack in a future conflict, and holding them responsible, becomes exponentially more difficult without agreed-upon investigation procedures. This environment of uncertainty and impunity could embolden rogue states or non-state actors, making biological weapons a disturbingly attractive option in asymmetric warfare. The potential for engineered pandemics, targeting specific populations or critical infrastructure, represents a truly dystopian scenario. In this dark vision of future warfare, the unaddressed weaknesses in the BWC regime, particularly the absence of strong protocols, become a critical vulnerability, paving the way for unimaginable horrors and the erosion of fundamental human rights on a massive scale. An influenza pandemic could place an extraordinary burden on healthcare systems & essential community services. Preparing for such a threat is an important priority[15].

Biological Weapons Convention (BWC)

The international legal framework concerning bioweapons is primarily anchored by the Biological Weapons Convention (BWC), a treaty that comprehensively prohibits the development, production, acquisition, transfer, stockpiling, and use of biological and toxin weapons. This prohibition extends to microbial or other biological agents and toxins that lack justification for peaceful purposes. Complementing the BWC is the Geneva Protocol of 1925, which specifically outlaws the use of bacteriological methods of warfare. Furthermore, the prohibition against the use of biological weapons is widely recognized as a principle of customary international law, binding upon all nations. International Humanitarian Law (IHL) principles, emphasizing the protection of civilians and the prohibition of indiscriminate attacks, are also critical in this context. UN Security Council Resolution 1540 reinforces these efforts by obligating all member states to prevent the proliferation of weapons of mass destruction, including biological weapons, to non-state actors. The development and potential use of bioweapons pose severe threats to a spectrum of fundamental human rights, most notably the right to life. Such weapons can also cripple healthcare systems, infringing upon the right to health, and generate widespread insecurity, undermining the right to security of person. Beyond immediate health impacts, biological attacks can disrupt essential services and damage livelihoods, thereby affecting the rights to an adequate standard of living. Some perspectives even consider the potential for severe environmental damage, raising concerns about environmental rights. Consequently, the existing legal frameworks, particularly the BWC, are

[15] aspr.hhs.gov/Pages/Home.aspx.

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essential for establishing a strong international norm against bioweapons and preventing their catastrophic consequences on human rights.

Administration for Strategic Preparedness & Response (ASPR) leads the nation's medical & public health preparedness for, response to & recovery from disasters & public health emergencies. ASPR constantly scans the horizon to define threats, whatever emergency may come next, whether natural or man-made[16] the importance of preparing for bio-terror attacks and influenza pandemics, highlighting the potential burden on healthcare systems. While it doesn't directly outline the legal framework, it implicitly points to the need for such frameworks in the context of bioweapons and their potential impact on human rights. The recent COVID-19 pandemic triggered fears & high-level, questionable accusations of covert biological warfare[17]."The fear of secret genetic weapons capability & use is not limited to malicious non-state actors. In what has been characterized as a sign of a 'new Cold War,' a Chinese Foreign Ministry spokesman suggested in March 2020 that 'the US Army may have brought COVID-19 to Wuhan.' (John Haltiwanger, 'The US & China Are on the Brink of a New Cold War That Could Devastate the Global Economy') The US Secretary of State responded in kind by alleging that the outbreak originated in a Chinese laboratory." (Berger, Mike Pompeo)

While the BWC is a cornerstone, other international legal instruments and norms are relevant:

A) **Geneva Protocol of 1925:** This protocol prohibits the use in war of asphyxiating, poisonous, or other gases, and of bacteriological methods of warfare. It complements the BWC by addressing the use of such weapons, while the BWC focuses on their development and possession.

B) **Customary International Law:** The prohibition against the use of biological weapons is widely considered a norm of customary international law, binding on all states regardless of their treaty obligations.

C) **International Humanitarian Law (IHL):** Principles of IHL, such as the prohibition of indiscriminate attacks and the obligation to protect civilians, are highly relevant in the context of bioweapons, which by their nature can be difficult to control and may have widespread effects.

D) **UN Security Council Resolution 1540:** This resolution obligates all UN member states to adopt and enforce effective measures to prevent the proliferation of weapons of mass destruction, including biological weapons, to non-state actors.

[16] Reuben Ananthan Santhana Dass, Bioterrorism: Lessons from the COVID-19 Pandemic report.
[17] Yelena Biberman, The Technologies & International Politics of Genetic Warfare.

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Human Rights Implications:

The development and use of bioweapons have profound implications for a wide range of human rights[18]:

1) **Right to Life:** Bioweapons are inherently designed to cause death and mass casualties, directly violating the most fundamental human right.
2) **Right to Health:** The deliberate spread of disease through biological agents can overwhelm healthcare systems, deny individuals access to necessary medical care, and cause long-term health consequences for survivors.
3) **Right to Security of Person:** The threat and use of bioweapons create widespread fear and insecurity, undermining the right of individuals to live free from violence and the threat of violence.
4) **Right to an Adequate Standard of Living**: Biological attacks can disrupt essential services, damage infrastructure, and destroy livelihoods, impacting the rights to food, water, shelter, and economic well-being.
5) **Environmental Rights:** Some analysts argue that the use of bioweapons could lead to "ecocide," causing severe and widespread damage to ecosystems and biodiversity, thus impacting environmental rights.

The research highlighting the need for preparedness and the potential strain on healthcare systems during a bio-terror attack or pandemic, underscores the importance of preventing the development and use of bioweapons to safeguard these fundamental human rights. The legal frameworks in place, particularly the BWC, aim to establish a strong norm against such weapons and prevent their devastating consequences.

Other Biosecurity Measures for Protection of Bioweapon:

1) The 2024 independent review of IGAB is underway & will provide a review report to Commonwealth, State & Territory Ministers responsible for biosecurity matters on findings & any recommendations for improvement. (Intergovernmental Agreement on Biosecurity Review) [19]
2) The IAP (the Inter academy partnership - Science Health Policy) General Assembly agreed to establish a Biosecurity Working Group in 2003, designed especially to link with the Biological & Toxin Weapons Convention (BTWC). Activities include the

[18] UDHR
[19] agriculture.gov.au/biosecurity-trade/policy/partnerships/igab/ intergovernmental-agreement-on-biosecurity

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promotion of responsible research practices & links with the Organization for the Prohibition of Chemical Weapons (OPCW).

A new IAP **Biosecurity Working Group (BWG)** was established in 2020. Current BWG members are from Argentina, Brazil, China, Egypt, Georgia, Germany, Ghana, Italy, Pakistan, Philippines, Russia, South Africa, Trinidad & Tobago, the United Kingdom & the United States.

In accordance with the precautionary approach undertaken in Principle 15 of Rio Declaration, the Cartagena Protocol mandates potential risks associated with modern biotechnology & the need for adequate level of protection & thus the necessity of the precautionary principle. DNA Profiling & analysis of body substances is considered to be a powerful technology that makes it possible to determine whether the origin or source of one body substance is identical to another. It is also helpful in establishing the biological relationship between individuals (living or dead).[20]

In this context, the Biological Diversity Act talks about Prior Consent to be taken from the government before using such natural biological resources for genetic engineering & research aimed at experimentation[21].The data generated is submitted to the Drug Controller General of India, who can use it while considering the release of drugs, vaccines, pharmaceuticals and other such allied products into the market[22].

The ICMR in its capacity as the Scientific & technical advisory body to Ministry of Health & Family Welfare, Government of India has formulated these "Guidelines for Government of India Safety Assessment Procedures for Foods."

Sec 4 of the 1989 Rules, DNA Safety Guidelines, it has the power to inspect, investigate & take punitive action in case of violations of statutory provisions through the nodal department of the State Pollution Control Board or the Directorate of Health or Medical Services. And The Institutional Biosafety Committee (IBSC) is established under the institution itself by the

[20] - Supra note 8
[21] Supra note 18
[22] Sreenivasulu N.S. & Arnak Sengupta 2010 "Biological Resources, IPR & Biodiversity: Manupatra Property Reports, 1(2): F35-F42

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occupier engaged in GMO research to oversee such research & Interface with the RCGM in regulating it.

National Biosecurity Policy and Action Plan 2020-2026[23]: To this end, our priority is to work closely with other countries and multinational organizations such as the Biological Weapons Convention International Support Unit (BWC ISU), European Union CBRN Centre for Excellence, Food and Agriculture Organization (FAO), World Health Organization (WHO) and World Organization for Animal Health (OIE), United Nations Office of Counterterrorism (UNOCT), amongst others.

Suggestions:

Protocols within the context of the Biological Weapons Convention (BWC) refer to legally binding agreements that could further strengthen the Convention's effectiveness. Unlike the BWC itself, which lacks a robust verification mechanism, potential protocols could establish procedures for monitoring compliance, investigating alleged breaches, and promoting transparency through information exchange and on-site inspections. Negotiations for such protocols have faced challenges, with differing views among states on the scope and intrusiveness of verification measures. However, the aim of these protocols is to enhance confidence in the BWC regime and deter the development and use of biological weapons by ensuring greater accountability and oversight among signatory nations. There is need of education and training in bio-risk management as a means of global health governance because effective implementation of biosafety and biosecurity measures can contribute not only to minimizing the risks posed by natural, accidental and deliberate disease but also to minimizing the potential for the misuse of life science research. Artificial intelligence is an emerging technology; however, the lack of specific laws and regulations highlights the urgent need to update biosecurity frameworks in line with technological trends. Failure to update biosecurity laws in accordance with technological advancements may exacerbate risks to biodiversity and global health security.

From a legal standpoint in 2025, strengthening the global framework against bioweapons terrorism requires a multi-pronged approach. Firstly, actively pursuing and finalizing robust protocols to the Biological Weapons Convention (BWC) is crucial. These protocols should

[23] National%20Biosecurity%20Policy%20and%20Action%20Plan%20

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include mechanisms for verifiable declarations, on-site inspections, and information sharing to enhance transparency and deter illicit activities. Secondly, universalizing the BWC and ensuring all nations enact strong national legislation criminalizing the development, production, possession, and use of biological weapons, as well as their transfer to non-state actors, is paramount.

Furthermore, international cooperation on intelligence sharing and capacity building for detecting, preventing, and responding to bio-terrorism incidents needs to be intensified. This includes harmonizing legal definitions of bio-terrorism and establishing clear extradition and prosecution mechanisms for perpetrators across jurisdictions. Finally, exploring the potential for an international legal framework specifically addressing bio-terrorism, perhaps through a supplementary protocol or a new convention Because BWC focuses on state actors, while bio-terrorism often involves non-state actors, new convention may be needed instead of protocols, could provide a more targeted and comprehensive approach to this evolving threat. This framework should emphasize accountability and the protection of human rights in the context of bio-security.

From a deterrence angle, legally binding BWC protocols with robust verification would increase the perceived risk of detection and punishment, dissuading states and non-state actors from pursuing bioweapons. From a prevention perspective, harmonized national laws and enhanced international cooperation on intelligence sharing and capacity building would strengthen early detection and disruption of bio-terrorist plots. From a response and accountability standpoint, clear legal frameworks for extradition and prosecution, potentially through a new international instrument, would ensure that perpetrators are held accountable, fostering justice and potentially preventing future attacks. Finally, from a human rights angle, a strengthened legal regime would reinforce the obligation of states to protect their populations from the devastating consequences of bioweapons terrorism, upholding fundamental rights to life, health, and security.

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