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Beyond the Biological Weapons Convention: Rethinking International Biosecurity Governance in the Age of Synthetic Biology

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ABSTRACT

The Biological Weapons Convention (BWC) remains the central international framework prohibiting biological weapons, but rapid advances in synthetic biology, genome editing, artificial intelligence-enabled protein design, and the wider diffusion of biotechnology are creating governance challenges that were not anticipated when the Convention was established. This paper examines whether the existing international biosecurity governance architecture is capable of addressing these emerging risks and identifies the institutional gaps that limit its effectiveness. Drawing on regime complex theory and the literature on institutional adaptation, the study uses a qualitative analysis of international rules, institutions, and governance arrangements involving states, international organizations, scientific communities, biotechnology firms, and other non-state actors. It argues that the BWC's absence of a verification mechanism, limited implementation capacity, and predominantly state-centric structure constrain its ability to address a rapidly changing and increasingly decentralized biosecurity environment. The analysis finds that governance has expanded through overlapping and largely voluntary arrangements rather than through comprehensive reform of the BWC. While these arrangements provide important regulatory and normative functions, their fragmented nature creates gaps in coordination, accountability, and risk management. The study therefore argues that effective biosecurity governance requires a layered and adaptive architecture that preserves the BWC's central normative role while strengthening its institutional capacity. It recommends minimum international standards for DNA-synthesis screening, greater formal integration of scientific and industry governance, and stronger coordination between the BWC framework and global health security institutions.

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Introduction

Biological weapons occupy a distinctive place in the arms control landscape because the underlying technology is inherently dual-use: the same scientific knowledge, equipment, and materials that enable vaccines, therapeutics, and agricultural innovation can, in principle, be redirected toward harm (Koblentz, 2011). The dual use nature of these products has always made the development of a robust prohibition regime difficult, and it has also become highly consequential in the last 20 years, as there is a growing convergence in the fields of synthetic biology, genome editing technologies, automated DNA synthesis, and artificial intelligence-assisted protein design, all of which have reduced the technical and financial barriers to the manipulation of living systems (Global Biodefense, 2025). What was once the preserve of state-run weapons programs and specialized research institutes being now, in principle, accessible to university laboratories, biotechnology start-ups, biohacker communities, and increasingly capable individuals working with commercial gene synthesis services and open-source computational tools.

The Biological Weapons Convention (BWC), which was opened for signature in 1972, was negotiated in a completely different technological and geopolitical context. It was the first multilateral treaty to ban an entire class of weapons of mass destruction, and it is a strong international norm: it is near universally signed and has contributed to the development of a robust international taboo against the use of biological weapons (Bulletin of the Atomic Scientists, 2011). However, the Convention was not intended to include a verification mechanism, and the 1995–2001 negotiation of a compliance protocol failed to take place, as the United States refused to participate, considering the proposal to be too intrusive on legitimate biodefense and commercial activity and too weak to detect covert violations with a high level of confidence (Non-proliferation Review, 2020; Nuclear Threat Initiative, 2001). The BWC has not established a standing verification body, a mechanism for investigating alleged BWC violations, nor binding rules concerning many of the technologies which today cause biological risk (Frontiers in Bioengineering and Biotechnology, 2026).

The central research question in this paper is whether the current international biosecurity governance framework, based on the BWC, can structurally address risks associated with synthetic biology and the convergence of synthetic biology and artificial intelligence. The main thesis stated here is that it's not, that's at least in isolation. In fact, the operational governance of biological risk has spread out to a multitude of export control mechanisms and national export control bodies, as well as industry self-regulatory mechanisms, codes of scientific conduct, and health security instruments, none of which were originally conceived to function as a unified system. This is not just a technical problem, it is a governance design issue of the fact that a treaty designed around state ownership of arms is a mismatch with a risk landscape increasingly shaped by diffuse, commercial and computational actors. The paper builds this argument by examining the institutional weaknesses and strengths of the BWC, the new governance failure drivers of technology, the stakeholders filling governance voids, and a set of policy recommendations to create a more adaptive governance architecture.

Theoretical Framework

This study draws primarily on regime complex theory and the literature on institutional adaptation to examine the changing structure of international biosecurity governance. Regime complex theory is useful for understanding governance settings in which multiple institutions, rules, and actors operate simultaneously without a single hierarchical authority or a fully integrated institutional structure (Raustiala & Victor, 2004; Orsini, Morin, & Young, 2013). Global health governance is often described as a regime complex involving the World Health Organization (WHO), international health law, intellectual

property regimes, and an expanding range of public-private partnerships (Springer Nature, 2024). This complexity is even more evident in the field of biosecurity where the Biological Weapons Convention (BWC) exists in parallel with the Australia Group, UN Security Council Resolution 1540, the International Health Regulations (IHR), and a variety of other voluntary standards by industry and academia (Namdeo, Aziz, & Friedman, 2026).

Regime complexity can be simultaneously "a blessing and a curse" for international biosecurity governance. On the other hand, a network of scientific, technical and managerial skills centers can facilitate the exchange of best practices, ideas, and resources between states, international organizations, academic institutions and private industry, particularly in the areas that are changing quickly, like synthetic biology and DNA synthesis, which demand a flexible and timely response (Namdeo et al., 2026). Fragmentation, however, can also result in duplication of effort, inconsistencies, confusion, and lack of oversight, especially when it comes to normative expectations and the distribution of responsibility and authority among many actors with different mandates (Springer Nature, 2024; Oxford Open Infrastructure and Health, 2023).

The second difference, between institutional adaptation and institutional constraint, relates to the capacity of international biosecurity governance to adapt to technological and political change. The authors stress that they do not consider the BWC to be a treaty that needs radical redesign, and that the BWC is not a failed treaty, but is a set of norms that are shaping and directing the continuing political processes. The analysis will thus be focused on variation in institutional effectiveness, specifically variation in the capacity of the international biosecurity governance complex to flexibly adapt the design of policies and institutional practice in response to new needs. The difference between policy design and institutional capacity, between goals and implementation is the key leverage point. To what extent international biosecurity governance systems and treaties can be implemented to achieve policy objectives is dependent on the ability of governments, organisations and institutions to operationalise bio-security through the development of consistent policy and procedure (Gillum & Moritz, 2025). With this approach, the study attempts to account for both the content of international biosecurity governance commitments and their implementation.

The BWC: Institutional Strengths and Structural Weaknesses

Strengths

The BWC's real significance, however, is symbolic; as a norm-setting instrument, it was the first treaty to ban an entire class of weapons; and it has helped to foster a culture of consensus (Bulletin of the Atomic Scientists, 2011). Universal participation helps to lend credibility to the treaty and to support global biosecurity governance. The creation of the Implementation Support Unit in 2007 provided the needed managerial support, and the Second Review Conference (SRC) introduced states with a forum to share information on biodefense programs, disease outbreaks and other topics. The 9th Review Conference took a positive step towards filling the normative gap with a decision taken at the meeting establishing an ad hoc working group to consider measures related to implementation and verification, a measure not taken since the 2001 meeting.

Weaknesses

The BWC's structural shortcomings are significant put against these accomplishments. It differs from the Chemical Weapons Convention in that it lacks a permanent inspectorate, there is no regular on-site verification and there is no specific process for investigating non-compliance allegations. The participation of CBM has remained around half of the parties to the treaty, including only around half of the States, even for the voluntary transparency function of the treaty. The failure of the 1995-2001 Ad Hoc Group negotiations left an enduring impression—whether the United States or another party ended up backing out, some scholars came to believe from the start that a

verification protocol would not be sufficiently intrusive for credible, legitimate biosecurity and commercial research, yet not strong enough to reliably detect deliberate violations (Non-proliferation Review, 2004; Non-proliferation Review, 2011). Review Conferences are held once every five years, and have often yielded very little in the way of substantive results, the Eighth Review Conference in 2016 being one of the low points.

Mention should be made in this paper's context to the BWC's normative architecture, which is based on the paradigm of state weapons programs with no operational mechanism that deals with the technologies that now drive biological risk. It does not provide detailed rules on the screening of gene synthesis as a gene technology, the responsibilities of commercial providers of gene synthesis, benchtop gene synthesis devices, or AI-assisted biological design. This generates a chasm between the "high-level" norms of biosecurity and the "ground-level" governance aspects of synthetic biology transactions that recent scholarship has labelled a gap. The Convention was never intended to operate in a context in which the parties are as likely to consist of the ministries of defence as of biotechnology companies, cloud labs and software developers.

Technological Drivers of the Governance Gap

Synthetic Biology and DNA Synthesis

In recent years, the use of automation, high throughput synthesis platforms, and error-correcting methods have significantly lowered the synthesis cost and complexity of custom DNA sequences (Frontiers in Bioengineering and Biotechnology, 2026). Historically, sequence screening was coordinated via a voluntary International Gene Synthesis Consortium (IGSC) and more recently through a new open source screening mechanism called the "Common Mechanism" developed by the International Biosecurity and Biosafety Initiative for Science (IBSI) developed by the National Academies Press (2021), and further coordinated by Gillum & Moritz (2025), which represents a baseline screening tool for providers. These arrangements are useful but temporary, adopted at uneven rates and not legally binding; indeed, one recent legal study concludes that private governance "can't replace the authoritarian systems that would need to be the basis for global biosecurity" because self-regulation is "too weak a foundation" on which the domain of biosecurity can be built (Journal of Law and the Biosciences, 2026). Even formal national commitments can be rescinded in a heartbeat, as was the case with the 2024 Framework for Nucleic Acid Synthesis Screening in the United States, which was also cancelled by executive order in 2025 (Gillum & Moritz, 2025).

Genome Editing and the Democratization of Biotechnology

CRISPR genome editing, which permits precise modification of the genome, has brought advanced life-science capabilities to a mass market, making it far more affordable and easier to access than previous methods; well beyond the reach of traditional state and elite academic institutions. On the one hand this diffusion is good in scientific terms and is scientifically and medically beneficial, on the other, it means that biosecurity risks cannot be addressed realistically through the controls that are specific to a limited number of state programmes or specialised facilities. In a world of low-cost, distributed, and capable biotechnology (Carnegie Endowment for International Peace, 2024), governance instruments based on lack of understanding and resources are becoming increasingly outdated. Given that it is no longer feasible to "wall off" biotechnologies or regard relevant knowledge as something that can be contained through secrecy, a shift toward a more multi-layered, multistakeholder governance framework is called for as opposed to traditional non-proliferation strategies that focus on the physical control of materials and facilities. (Carnegie Endowment for International Peace, 2024).

Artificial Intelligence and Generative Protein Design

AI and synthetic biology is the most significant and unregulated field. In principle, generative AI tools that can produce novel proteins can lead to a

corresponding drop in technical barriers for the production of harmful biological agents, and an existing cross-sector study in 2025 revealed that current DNA synthesis-screening, which is mainly based on homology-based algorithms and a comparison of ordered sequences with known threat agents, is increasingly becoming insufficient for sequences generated by AI that might not closely resemble anything in known threat databases (Global Biodefense, 2025). In this governance space, the issue is that the current governance structures are missing a structural component: Biosafety governance has focused primarily on physical agents and laboratory practice, whereas AI governance has largely been centered on privacy, algorithmic fairness, fairness in general, and the regulation of AI systems (Springer Nature, 2025). While proposed mitigations suggest layers of controls (risk tiered access to high capability biological design models, systematic red-teaming prior to release, enhanced screening of short DNA fragments, audit logging, international capacity-building), the literature also indicates that the evaluation metrics and monitoring standards for these measures are still underdeveloped (Springer Nature, 2025).

Stakeholders in the Governance Architecture

States and the Multilateral Process

The BWC is still formally a state led agreement, with national implementation (export controls, biosafety legislation, and law enforcement cooperation) remaining relevant, though the 2022 BWC agreement establishing a Working Group on compliance and verification does show the potential and the timeliness of state-led multilateral reform. The Working Paper on Tianjin Biosecurity Guidelines, jointly sponsored by China and Pakistan during the Ninth Review Conference (Ministry of Foreign Affairs of the People's Republic of China, 2021), is a testament to the fact that mid-sized and emerging powers can engage in an agenda-setting capacity even when major powers are hesitant to adopt new verification commitments.

International Organizations and Regime Fragmentation

The WHO's biosafety guidance, the WHO's International Health Regulations, and the newly adopted WHO Pandemic Agreement all constitute a parallel, and at least in part overlapping, governance pathway that has a focus on public health emergencies and not on deliberate misuse. The Pandemic Agreement has demonstrated a reasonable level of procedural inclusiveness, with only moderate results in terms of robustness and expected effectiveness, while analysts have pointed to the prospect of exacerbating fragmentation in the global health security system (ENSURED Research Report, 2025). This is consistent with a wider trend seen across global health governance scholarship, whereby the role of the WHO has become increasingly diffused and fragmented, despite the increasing scope of actors involved in health security (Springer Nature, 2024).

The Scientific Community

Scientists and scientific institutions also have become increasingly formal actors of governance in their own right. Ten principles that outline ethical standards, knowledge of the applicable legal framework, responsible conduct of dual-use research, and international cooperation in science were also developed by an international group of scientists and endorsed by the Inter Academy Partnership, as stated in the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists (Trends in Microbiology, 2022). The authors of these have urged the BWC to formally adopt the guidelines, an institutional acknowledgment of the linkage between bottom-up scientific self-governance and the BWC regime. However, follow-up research has shown that biosecurity education is key to effective implementation, and that existing educational infrastructure was very widespread and extensive in some aspects, but was not sufficiently available and very much in need of updating and translation in order to have a truly global reach (ScienceDirect, 2022).

Biotechnology Companies and Non-State Actors

Commercial DNA synthesis companies are in a really special position, as they are at the intersection of digital genetic information and physical biological material. While a business-driven approach to screening via the IGSC and, more recently, the Common Mechanism may make sense for the industry, the voluntary nature of these standards creates barriers of uneven uptake, no meaningful enforcement and competition from providers unwilling to bear compliance costs (Journal of Law and the Biosciences, 2026; National Academies Press, 2021). More broadly, there are also concerns that multistakeholder governance arrangements that formally involve industry, as in this case with WHO, may compromise effective governance, as evidenced by industry's history of undermining policy development in other health governance fields (Globalization and Health, 2025). A conundrum of industry cooperation but also the danger of regulatory capture is constantly recurring in biosecurity governance discussions, and it has not yet been resolved by the existing governance institutions.

Discussion: Toward an Adaptive Governance Architecture

The evidence in this section supports a central claim: the BWC's design logic (a prohibition regime which was state-centric and lacked an operational verification) was suitable to the weapons programs of the twentieth century but did not fit the environment of commercial gene synthesis companies, decentralized scientific communities, and artificial intelligence developers. This is no excuse to walk away from the BWC. In terms of its normative influence of condemning biological weapons and establishing a legal basis for national implementation, it is valuable and hard to duplicate. Instead, the Convention must be read within a larger regime complex that includes other instruments such as export control agreements, instruments pertaining to health security, industry screening standards, and scientific codes of conduct, which should be deliberately introduced into the Convention, not necessarily in the same manner.

From the analysis three tensions are highlighted. First, there is longstanding lack of capacity to implement screening requirements, with newly developed sequence-level screening obligations potentially overwhelming under-resourced institutions and resulting in "paper-thin" oversight, especially in lower-resource countries (Gillum & Moritz, 2025; Frontiers in Bioengineering and Biotechnology, 2026). Second, this is the governance gap between AI and biosecurity, in which there is no clear jurisdiction over existing biosafety frameworks and AI governance regimes (Springer Nature, 2025). Third, there is an unaddressed legitimacy issue over the proper role of industry in standard-setting, in light of the need for provider cooperation and prior evidence that standards-setting in other global health areas is susceptible to regulatory capture (Globalization and Health, 2025). These are all interrelated and must be taken up by an adaptive governance architecture, not dealt with individually.

Policy Recommendations

Five recommendations are offered in the following section for enhancing international biosecurity governance, based on this analysis, that can be implemented before an unlikely renegotiation of the BWC itself.

States parties should first formally adopt and operationalize the Tianjin Biosecurity Guidelines through the BWC review process, in conjunction with continued investment in biosecurity education programmes, which are translated, regionally adapted and incorporated into life sciences education programmes, to address the gaps in biosecurity education identified in existing biosecurity education programme surveys (ScienceDirect, 2022).

Second, a minimum baseline standard for DNA and RNA synthesis screening should be internationally harmonized, and if feasible, integrated into BWC review outcomes or a complementary instrument: Voluntary adoption to this point should be moved to binding

commitments for accredited providers, with technical assistance and shared screening infrastructure necessary to ensure that lower resource providers and jurisdictions are not disadvantaged (Journal of Law and the Biosciences 2026, Frontiers in Bioengineering and Biotechnology 2026).

Third, screening should shift from homology-based sequence comparison to function-based and AI-driven screening techniques that could identify novel, AI-generated sequences not closely related to known threat agents, as suggested by the recent cross-sector research and collaborations (Global Biodefense, 2025).

Fourth, a specific coordination process should be established between the BWC Implementation Support Unit, the WHO health security instruments and relevant AI governance bodies, with the intention of bridging the jurisdictional divide between biosafety and AI governance, and not merely leaving the issue between the existing mandates (Springer Nature, 2025).

Fifth, any increased involvement of biotechnology industry actors in standard-setting should be designed to include explicit conflict of interest protection measures and independent evidence-based review, based on the documented problems of corporate influence in other multi-stakeholder health governance processes, to ensure that the industry is not able to exert undue influence over the content of biosecurity standards (Globalization and Health, 2025).

Conclusion

The Biological Weapons Convention (BWC) remains an essential normative foundation of international biosecurity, but its institutional framework was not designed for a risk environment transformed by synthetic biology, genome editing, artificial intelligence, and the wider diffusion of biotechnology. This study hypothesized that the response to the identified governance gap would take the form of either comprehensive multilateral reforms or limited adjustments within the framework of the existing system. However, the analysis has demonstrated that the problem was addressed through a varied set of measures, which led to the emergence of a fragmented regime complex. This consists of industry screening practices, scientific codes of conduct, export control regimes and other global health security initiatives, among others. These steps have helped to make strides in biosecurity governance, but their 'one-off' and voluntary nature will pose challenges for the future of global health security. The analysis is consistent with the suggestion that rather than discarding the BWC for uncoordinated measures or modifying the treaty in response to new threats, it is necessary to enhance the role of the treaty in the global framework of biosecurity governance. This could be done by improving coordination and oversight mechanisms within the BWC so that the involvement of the scientific, commercial and national security communities in international biosecurity governance is more meaningful and flexible without compromising its fundamental principles.

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