

# Controlling the Transfer of Biotechnology in the Age of Strategic Competition

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## **I. Introduction**

Advances in the life sciences, while contributing to progress in the medical and biotech industry, could be intentionally or accidentally misused with destructive economic, social, and environmental impacts, posing serious challenges to efforts to prevent the spread of biological weapons (Tanaka, 2019). The United Nations Secretary-General’s disarmament agenda published in 2018 raises specific concerns about “the ability of new technologies to ease barriers to the access and use of prohibited weapons, such as may be the case with synthetic biology and gene editing” (United Nations Office for Disarmament Affairs, 2018, p. 52).

More recently, the convergence of biotechnology with emerging technologies — including additive manufacturing (AM, often also referred to as 3D printing), artificial intelligence (AI), and robotics — has become a particular focus since these technologies hold tremendous promise but also increase the possibilities for the misuse of biotechnology and the proliferation of biological weapons (Brockmann et al., 2019, p. 1). These technologies and tools are inherently “dual use” in nature, as they can be used for both peaceful and military/unlawful purposes, and the key difference is user intent. In response, states are striving to prevent the development, transfer, and use of biological weapons and associated risks through multilateral and unilateral measures, including export control measures; biosecurity legislation, guidelines, or standards; and mechanisms to monitor relevant technological developments.

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The development of biotechnology and other emerging technologies has led to strategic competition among states and a renewed interest in “economic statecraft,” the use of economic means to pursue political goals (Baldwin, 2020). While there are many historical examples of the realization of diplomatic and security objectives through technology transfer controls, in the post–World War II world, the pursuit of political objectives through restricting economic activity has generally been positioned as an exceptional measure for nonproliferation purposes. Among nations with advanced science and technology, there has been a growing recognition of export control as a necessary tool to protect their own critical industry and to gain the upper hand in strategic competition. As strategic competition intensifies, especially over emerging technologies, companies or researchers are increasingly required to be sensitive to foreign investment and the transfer of intangible technology (i.e., knowledge and information) in business and research. As the intensifying struggle for supremacy among nations revolves around science, technology, and innovation, controlling intangible technology transfer (ITT) is a challenging issue for many states.

This article examines how states aim to secure their strategic priorities through transfer controls on biotechnology — a key element in this era of strategic competition — and the impact of these efforts on the nonproliferation of biological weapons. It is organized into three sections. The first section examines the renewed security concerns caused by the recent convergence of the life sciences with emerging technologies. The second section analyzes the export control policies of states — specifically, the United States (US), China, the European Union (EU), and Japan, which have recently developed new or amended legislation for emerging technologies — and their impact on nonproliferation. The final section discusses global, multilateral, and unilateral export control efforts to highlight the importance of international cooperation even in the era of strategic competition.

## **II. Biotechnologies and challenges for export control**

Recent breakthroughs in what is often categorized as “emerging technologies”

have occurred in genome editing, gene drives, and synthetic biology. Yet there is also concern that the resultant advances in medical technology and biotechnology could be intentionally misused, with destructive economic, social, and environmental impacts — such research is called the “Dual Use Research of Concern” (DURC) (Himmel, 2019). Further, the development and commercialization of the CRISPR-Cas9 genome editing tool has significantly lowered barriers to access, attracting diverse actors as national regulatory agencies struggle to keep pace with the rate and scope of developments (Kavanagh, 2019).

In addition, there has been growing concern that research publications could educate and empower malicious actors, especially since 2012 when scientists in the US and in the Netherlands published their research in prominent journals (Herfst et al., 2012; Imai et al., 2012). Both had succeeded in genetically engineering strains of the avian flu virus (H5N1), which was originally only transmissible to birds, so that it could be transmitted to mammals. This was a type of “gain of function” (GOF) research, which involves designing new biological components by adding new functions to genes that exist in nature (Garret, 2013). Their studies triggered an unprecedented debate and strong public concern over whether the results should have been published and, more fundamentally, whether such experiments should have been conducted (Charatsis, 2015), as terrorists could use the results to manufacture biological weapons or cause a devastating pandemic.

In response, the then newly established National Scientific Advisory Board for Biosecurity (NSABB) in the US was called to consider the potential threat posed by these publications. Conversely, in the EU, it was the Dutch authorities who concluded that export authorization should be required for the publication of the manuscripts. The scientific community consequently declared a voluntary moratorium on certain types of controversial experiments, until the risks and benefits of research on altering a pathogen to make it more transmissible or deadly could be reassessed. Meanwhile, in October 2014, the US government froze its research funding for 19 months — particularly for GOF research — while the NSABB conducted a risk assessment. Its final report in May 2016 indicated that some research should not be conducted because the risks outweigh the justifiable

benefits; that research permission should be based on an assessment of the risks and expected benefits for each experiment; and that while scientific merit is a central consideration in the assessment, legal, ethical, public health, and social value should also be comprehensively considered (National Institute of Health, 2016).

In addition, the convergence of GOF research or DURC with other emerging technologies such as AI and AM raise challenges for biological arms control and international security. AI provides cognitive capabilities to multiple types of technology, including weapon systems (Brockmann et al., 2019), and AM, also known as 3D printing, has potential applications in the medical field. In particular, bioprinting, which combines AM and synthetic tissue production techniques, is one of the most promising technologies for regenerative medicine.

These technologies have grown rapidly, but the full range of their practical application is yet to be elucidated. Emerging technologies may have great strategic value and the potential to be adopted for both military and non-military industrial purposes (Himmel, 2019). The convergence of biotechnology with AM and AI could facilitate the development or production of biological weapons and their delivery means, potentially creating new risks for bioweapons control and biosecurity. As the development of these new technologies is driven primarily by the civilian and private sectors, it is difficult for the government to control the research directly.<sup>(1)</sup> Governments are thus trying to exert control by, for example, directly funding R&D or controlling funding and foreign investment in key companies, but they may not have the influence that they previously held in strategic industries (Brockmann et al., 2019).

The fact that most of these technologies can be easily transferred in the form of knowledge or digitally further complicates the control issue. As digital transfers

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(1) According to the AI Ethics Guidelines Global Inventory (AlgorithmWatch, 2020), which was last updated in April 2020, among 167 ethics guidelines compiled globally, most were published in northern and western Europe, including EU (72), followed by North America (50) and East Asia (9). Eight of these were governmental binding agreements, and the rest were recommendations (115) or voluntary commitments by private companies or academia (44). This indicates the difficulty of controlling such technology with enforcement measure by governments.

and other types of ITTs are more difficult to control than traditional transfers of goods, the prevailing export and customs controls and visa screening may no longer be sufficient barriers. Existing frameworks for the control of biological weapons cover only a limited range of the direct and indirect risks outlined above (Brockmann et al., 2019). While many of these technologies are being developed by companies based in the US and China, technological decentralization and democratization have made biotechnologies available to any consumers globally and progressed to a point where it is now possible for high school students to learn how to edit the genetic code (Pauwels, 2019, p. 9). Despite developments in automation and digitization, fully exploiting the potential of AI and AM technologies requires a great deal of specialized expertise and tacit knowledge that cannot be obtained simply by reading records or laboratory procedures, making internal corporate compliance mechanisms more important than ever.

### **III. Strategic competition and export control**

#### **1. Expanding the scope of export control**

China's rapid economic and, by extension, military rise in the early 2000s revived the concept of the conventional military superiority of the former Soviet era. The 2018 US National Defense Strategy noted that the US faced "an increasingly complex global security environment, characterized by overt challenges to the free and open international order and the re-emergence of long-term, strategic competition between nations" (Mattis, 2018). At the heart of this strategic competition are the emerging technologies, which are commonly attributed with enabling or disruptive qualities. They include production technologies such as AM; advanced biotechnologies such as synthetic biology and gene editing; and applications of computing capabilities or machine learning, including AI (Brockmann, 2018).

Free trade was the foundation of the world order after World War II. Globalization, which has accelerated since the 1980s, has stimulated the movement of not only goods but also capital. Consequently, production bases have been moved from the Global North to countries with low production costs.

This has led to the hollowing out of industries in the former and an increase in incomes at many levels in the latter. After the Cold War, the World Trade Organization (WTO) — originally, the General Agreement on Tariffs and Trade (GATT) — was created. This further promoted free trade and expanded the global supply chain network (Suzuki, 2020). Since then, the world has been based on free trade, and the use of economic pressure, such as imposing export controls or economic sanctions, has been regarded as an exceptional practice used to induce other countries to change their behavior. This is known as “economic statecraft,” and has been viewed as contrary to the rules of free trade (Suzuki, 2020).

Nonetheless, with the increase of tensions between/among nations, the WTO, which is supposed to ensure that the rules of free trade are followed, has become dysfunctional and the opportunity to punish those for not following the rules has been lost. In addition, there is a growing tendency for governments to use the “security exception” provisions under Article XXI of the GATT at the WTO in the name of national security, in order to justify barriers to trade and other behaviors (Prazers, 2020). Governments also increasingly use import and export regulations to address supply chain vulnerabilities, foreign components, and applications under the pretext of national security (Aggarwal & Reddie, 2021), as well as trade measures to manage strategic sectors of their economies.

Export controls were used as an economic statecraft tool during the Cold War, by limiting access to sensitive goods and technologies. They were initially deployed to help maintain technological advantages and prevent the spread of weapon technologies to adversarial states, with a view to maintaining military superiority. The Coordinating Committee for Multilateral Export Controls (CoCoM) was established by the Western Bloc to prevent the spread of strategic goods and technologies to the Eastern or Communist Bloc. With the end of the Cold War, the primacy of military superiority as the *raison d'être* of export control policy became diffuse and subordinate to nonproliferation (Jones, 2020). The focus of export controls shifted to preventing the proliferation and means of delivery of weapons of mass destruction (WMDs), as well as the destabilizing accumulation of conventional weapons through the establishment of multilateral

export control regimes. Each of the four regimes — Nuclear Suppliers Group (NSG) for nuclear materials, Australia Group (AG) for chemical and biological substances, and the Missile Technology Control Regime (MTCR) and Wassenaar Arrangement (WA) for conventional weapons — maintains one or multiple control lists specifying the goods and technologies that should be subject to licensing requirements in its area of concern.

Centered around these export control regimes, list-based export controls have been employed to limit the misuse and irresponsible and illegal transfer of conventional weapons, WMDs, and their delivery means (Brockmann, 2018). These regimes are not codified in legally binding agreements, but the participating states implement the guidelines and control lists through their national laws. The regimes have come to function as key norm setters, not only for participating states but also for non-participating states. As such, a growing number of states are voluntarily adhering to the guidelines and adopting the control lists (Brockmann, 2019b).

Since the inception of the regimes, the coverage of supply-side controls has significantly expanded. Beyond the creation and implementation of licensing requirements for exports of specific lists of goods and technologies, it now includes end-use and end-user controls, and controls on technology and the instruments to enforce them, such as compliance audits (Brockmann, 2019b). If carefully designed and targeted and effectively applied, export controls can also increase states' oversight and awareness of flows of critical goods and strategies, regardless of license denials being issued (Aggarwal & Reddie, 2021). States are thus increasingly seeing technology transfer controls as a useful tool to protect their critical industries, regulating exports and enacting domestic regulations on foreign direct investment (FDI) in the name of national security.

## **2. State responses to strategic competition**

### **(1) United States**

China's economic rise has elicited an increasingly aggressive response from the US for over a decade. While the existing export controls for WMDs

and military items remain intact, China’s rapid technological industrialization, particularly its Made in China 2025 industrial policy, has led to a dramatic reorientation of US export and FDI regulations (Jones, 2020).

The inclusion of critical technology in export controls, which was primarily based on materials, dates back to a 1976 report by the Defense Science Board Task Force on Export of US Technology (the “Bucy Report”), chaired by Fred Bucy. In defining “critical technologies,” the report established guidelines that: (1) advocate the control of design and manufacturing know-how, as opposed to finished products; (2) concentrate on “active” transfers (e.g., transfers of technology in which East–West interaction may be most intense), as opposed to “passive” transfers; and (3) focus on technology that represents a “revolutionary” as opposed to an “evolutionary” advance for the receiving nation (Jones, 2020). Ultimately, it recommended refocusing export controls on the most sensitive dual-use products rather than on all. Therefore, export regulators began to consider “technologies,” especially those “critical” to military superiority, differentiating between consequential (“revolutionary”) and mundane (“evolutionary”) technologies and identifying where the US was leading in the former (Jones, 2020).

The Export Administration Act (EAA) of 1979 was enacted in line with the above recommendation. It was repealed by the Export Control Reform Act (ECRA) of 2018, which was designed to link export controls with FDI, and to identify and control “emerging and foundational technologies” (Jones, 2020). Section 109 of the ECRA further instructs that:

The President shall ... establish and ... lead a regular, ongoing interagency process to identify emerging critical technologies that are not identified in any list of items controlled for export under United States law or regulations, but that nonetheless could be essential for maintaining or increasing the technological advantage of the United States over countries that pose a significant threat to [its] national security. (ECRA, s. 109)

However, the difficulty of controlling AI, AM, and biotechnology, for example, is that they are neither weapons nor a clearly defined component in



current WMDs or military stocks (Jones, 2020). As their military applications are still purely speculative, their national security impacts have not yet been evaluated. This uncertainty and ambiguity make emerging technologies difficult if not impossible to define and govern from an export control perspective (Evans, 2018).

The government has also increased its regulatory role in FDI, passing the Foreign Investment Risk Review Modernization Act (FIRRMA) in 2018 to expand the oversight procedures of the existing Committee on Foreign Investment in the United States (CFIUS) to include foreign activities in the US market. This applies to any involvement in business decision-making and even to minority stakes in US venture capital and private equity firms involved in critical technology (Aggarwal & Reddie, 2020). Thus, even transactions that have not been made by a foreign-controlled company can still be subject to disclosure, review, and investigation (Aggarwal & Reddie, 2021).

Under the new law, the Treasury Department and other enforcement agencies will have to decide which technologies will be subject to more stringent scrutiny and controls and whether some countries, particularly allies, will be exempt. Companies will have to modify their procedures and audit processes regarding foreign investments and the resulting voluntary declarations to CFIUS review. Thus, policymakers and companies must strike a difficult balance between maintaining an open investment environment and considering national security (Aggarwal & Reddie, 2021).

## **(2) China**

China has adopted a multifaced state capitalist approach, characterized by direct control of strategic sectors, party control over personnel, a market foundation for a large part of the economy, extensive industrial policy formulation by the government, and state control over finance (Aggarwal & Reddie, 2020). With Xi Jinping as head of state, the party leadership, while acknowledging that the market plays a decisive role in the economy, has pledged to “persist in the dominant position of public ownership” (Central Committee of the Communist Party of

China, 2014). Accordingly, bureaucrats and party officials make investment decisions through government-guided funds to carry out Xi Jinping's Made in China 2025 initiative, such that China can become a global leader in advanced technologies (Aggarwal & Reddie, 2020). Against this backdrop, innovation in dual-use technology is an integral component of China's security strategy.

In order to pursue the priorities set in its 14th Five-Year Plan (Stanford Cyber Policy Center, 2022), the Chinese government has enacted a set of interrelated laws and measures since January 2020 to strengthen its control over economic activity in areas that it considers important for economic competitiveness and national security. In December 2020, a new Export Control Law, which includes several provisions that aim to counter the US government's use of export control authorities to restrict the transfer of US dual-use technology to China went into effect (Congressional Research Service, 2021).

The Export Control Law gives the government new policy tools and justifications to deny and impose conditions on foreign commercial transactions both inside and outside of China on the grounds of national security and interests. It also gives the government new rationales and processes for imposing conditions on business-to-business transactions, transactions within joint ventures and other partnerships, and export and offshore transactions. In addition, the law authorizes the government to impose export restrictions in retaliation for the actions of other countries, to impose temporary (up to two years) export restrictions on items not on the restricted list, and to broadly justify its actions with several open-ended provisions. The law also contains provisions that press for China's participation in international discussions, regimes, and rulemaking on export controls based on the principles of equality and reciprocity, indicating the possibility of more moves to set global rules and norms in its favor.

To reinforce the new export law, China amended the Catalogue of Technologies Prohibited or Restricted from Export in August 2020, issued the State Council-approved Order on Provisions on the Unreliable Entity List in September 2020, and issued the Measures for the Security Review of Foreign Investment in December 2020, which came into effect in January 2021. This

strengthened the government's role in promoting and coordinating national economic security measures to enhance its global economic, technological, and military leadership, and to control the associated core technologies and global supply chains (Congressional Research Service, 2021). The measures also include extraterritorial reach to counter trade and national security policy instruments and actions that the US and other governments have applied against China. China's new trade measures attempt to create parity with the US by mirroring certain US authorities and practices in areas such as export controls, foreign investment screening, and sanctions, although it is believed that the government already has broad authority in these areas (Congressional Research Service, 2021).

### **(3) European Union**

The EU's basic export control policy is based on the principle of free trade, but from the perspective of security and the nonproliferation of WMDs, strict regulations are imposed on the export of military items (e.g., weapons and missiles), and dual-use items, including goods, software, and technology. Since the early 1990s, the EU has taken steps to increase the coordination and convergence of the export controls of its member states, whose national export control laws and regulations are based on common EU laws.

Regulation (EC) 428/2009 in 2009 was motivated by shared positions among EU member states on security policy objectives, including restrictions on exports of military-relevant technology to China. Thus, its dual-use export controls expanded their original focus on preventing illicit transfers to WMD programs to strengthening controls on emerging technologies such as AI and AM (Bromley & Brockmann, 2021). On September 9, 2021, a new version of these dual-use regulations entered into force, expanding the mechanisms that allow member states to make additional dual-use items to national list-based controls, to address the risks posed by emerging technologies and terrorism.

The EU is also developing a framework to harmonize the disparate FDI regimes of its member states. Currently, only 14 member states have national security screening procedures for FDI. Germany, for example, which is consistently

ranked as one of the most attractive investment destinations, has welcomed FDI in most cases with few restrictions from a national security perspective. However, the German government has increasingly strengthened its national security screening of inward FDI in recent years, in reaction to an increasing number of high-risk acquisitions of German companies by foreign investors, particularly from China (United States Department of State, 2021). By the end of December 2018, the scope of its FDI screening was expanded to include M&A activity by non-European investors when acquiring more than 10% of the voting rights in a sector with a potential impact on national security (United States Department of State, 2021).

As a result of these developments in Germany, the EU announced a draft agreement in November 2018 on the establishment of a framework to screen FDI entering the EU. It calls for an exchange of information on best practices, rather than a single common policy, and allows the European Commission to issue an opinion in cases concerning several member states (Aggarwal & Reddie, 2020). Its scope includes critical infrastructure and technologies, robotics, AI, cybersecurity, dual-use products, media, and broader infrastructure.

#### **(4) Japan**

For many years, Japan's economic policies have focused public investment on strategic sectors of its economy. In particular, vulnerability in the face of the US oil embargo during World War II and two oil crises in the 1970s led its leaders to prioritize building up energy reserves and diversifying energy sources. Japan has pursued constitutional pacifism since the end of the war, and its economic sector is also one of the most liberal in pursuing its strategic goals — Japan led the world in FDI in 2019, and its official development assistance to the Global South through 2017 accounted for more than 40% of the global total, as measured by the Organization for Economic Cooperation and Development.

In response to China's growing geo-economic influence in Asia, in May 2017, Japan amended the Foreign Exchange and Foreign Trade Act (FEFTA) to strengthen penalties for unauthorized exports and technology transactions. It

also strengthened its FDI regulations, owing to concerns about overseas outflows of security-related dual-use technologies and items associated with accelerated business internationalization. In November 2019, Japan further passed a bill to lower the trigger for state reviews of inward FDI in Japanese companies from 10% of the shares of eligible companies to 1% in 12 core sectors.

Subsequently, in May 2020, Japan announced factors for consideration regarding prior notification for investigating FDI and designated acquisitions in accordance with the FEFTA. Further, in April 2020, Japan established a new unit within the National Security Secretariat (NSS) responsible for economic national strategy or economic statecraft. Its purpose is to coordinate government policy on issues such as infrastructure investment and the protection of sensitive technologies. The unit is seen as one of Japan's most significant structural reforms in recent history, integrating economic policymaking with the national security bureaucracy.

In order to address concerns that sensitive security-related dual-use technologies may be leaked via human interactions, in June 2021 an interim report of the Subcommittee on Security Trade Control of the Subcommittee on Commerce and Trade of the Industrial Structure Council recommended a review of deemed export control (Article 25, Paragraph 1 of the FEFTA). In response, the Service Circular was revised to clarify the concept of deemed exports from May 1, 2022. Deemed export control is a system to control transactions providing certain sensitive technology to “non-residents” in Japan for the purpose of maintaining international peace and security, and requires prior permission from the Ministry of Economy, Trade and Industry (METI).

In the past, not only Japanese but also foreign nationals working in offices in Japan were considered “residents,” between whom the provision of technology was not subject to deemed export control management. Therefore, the provision of technology within a company was, in principle, exempted. In addition, since foreign nationals such as researchers and students who had been in Japan for more than six months were also considered “residents,” the provision of technology by universities or research institutes to them was sometimes excluded from

deemed export control. The recent clarification of “deemed exports” clarifies the relationship between “residents” and “non-residents,” and stipulates that METI approval is required when providing sensitive technology controlled under the FEFTA, even for those residents who have employment contracts with foreign governments and are obligated to obey the orders of such governments or foreign laws; those who receive large amounts of money or other significant benefits from foreign governments; and those who receive instructions or requests from foreign governments regarding their activities in Japan.

#### **IV. Challenges to ITT control**

The current governance framework in biosecurity and biological weapons control includes extensive treaty regimes and other monitoring and self-regulatory instruments. The principal arms control treaty on biological weapons is the Biological and Toxin Weapons Convention (BWC), which entered into force in 1975. The BWC prohibits the development and production of biological weapons and requires States Parties to implement measures for the nonproliferation of biological weapons. UN Security Council Resolution 1540 also obligates all UN member states to implement measures for the nonproliferation of WMDs to ensure that such weapons are not developed and produced by non-state actors. Furthermore, dual-use biological technologies are subject to international export controls. The AG focuses on biological and chemical supplies, while the WA regulates the production of dual-use technologies, including those that may contribute to the development of military capabilities.

Conversely, there are no precise criteria or defined guidelines to clarify how to assess technologies and regulate exports to address emerging technologies (Himmel, 2019). Nor is there a single harmonized international framework available for the regulation of emerging dual-use technologies. AM is currently being discussed in all multilateral export control regimes, including AG and MTCR, either as a possible subject of dedicated controls or as part of the review of science and technology in their exchange of information (Brockmann et al., 2019). There are no dedicated controls or other governance tools specific to the

development, use, or trade of bioprinters or AM equipment for the production of controlled equipment related to biological weapons.

Emerging technologies are widely recognized as creating potential threats that require a rapid response. The pace of development in these fields places additional demands on the ability of national export control systems to respond effectively and appropriately. Many of the emerging technologies cut across the traditional boundaries of nonproliferation governance instruments, institutions, and regimes, but they are still discussed separately in each regime. Additionally, there is an overlap of already established technologies in the control lists of some regimes (Brockmann, 2019b).

While export controls are currently a focus of regulatory discussions in the AM context, a more comprehensive approach is needed to address the challenges that arise in connection with biological weapons. As such, BWC and AG discussions must also further address the role of research ethics and risk mitigation procedures in relevant research areas (Brockmann, 2019a). This would include greater emphasis on raising awareness of the possible weapons applications — in relevant universities, research institutions, and the DIY community — as well as strengthening industry compliance and due diligence standards. Thus, states need to work with all stakeholders and carefully monitor the delicate risk situation they currently face in order to prevent emerging technologies from becoming a factor in biological weapons proliferation. Furthermore, the increasing pace of ITT, including in the biological field, has created the need to adjust existing export control structures. This is true not only for the electronic transfer of biotechnology (e.g., sending digitized biological information to a cloud laboratory that conducts experiments), but also for the transfer of potentially sensitive knowledge and know-hows through scholarly lectures, publications, science education, and all forms of scientific exchanges, such as study visits and joint projects, and development assistance in the sciences (Himmel, 2019).

The current trends of economic statecraft focusing on industrial policy, trade measures, and new FDI regulations in strategic competition raise the issue of how countries might cooperate on a multilateral basis to address the external impact

of such policies. The potential for the development of one or more international regimes to address economic statecraft may need to be discussed. The emerging governance model must necessarily reconcile the inherent limitations of export controls with the economic and political realities of accelerating technology diffusion and global supply chains that do not adhere to the Westphalian model (Jones, 2020).

## **V. Conclusion**

The purpose of this paper was to examine how states are attempting to ensure their strategic priorities in biotechnology through transfer controls in an era of strategic competition over emerging technologies and how these efforts affect the nonproliferation goals of biological weapons. In recent years, rapidly developing technologies in the life sciences have been classified as emerging technologies that, while contributing to the development of the medical and biotechnology industries, have a dual-use nature that can have destructive effects on economic and social activities and the environment if the same technologies are intentionally misused. In addition to the risk of misuse of the technology itself, such technologies are linked to the concern that public disclosure of the technology and research results could educate and empower malicious actors. Furthermore, the convergence of GOF research and DURC in the life sciences with other emerging technologies, particularly AI and AM, poses serious challenges to biological weapons control and biosecurity. In particular, these innovations are primarily driven by the private sector, making it difficult for governments to manage them, and most of these emerging technologies are in intangible forms such as digital information, which makes the management of funds for R&D or controlling ITT an important issue.

The management of such biotechnology, coupled with the management of technology in the strategic competition triggered by China's rapid economic and military rise, has become a major policy agenda of economic statecraft for many states in the Global North. The international economic environment since the end of the Cold War has been one in which free trade is the basic rule, and the focus of



export control has been on preventing the proliferation of WMDs and their means of delivery through the establishment of multilateral export control regimes. In contrast, in strategic competition, governments increasingly use import and export controls to address supply chain vulnerabilities dealing with foreign components and applications on national security grounds. This paper provided an overview of how the US, China, the EU, and Japan have enacted or amended laws related to emerging technologies to address strategic competition. It is clear that they are seeking to manage ITTs in addition to their existing export controls that focus on goods, through the control of FDI and strengthening the control of person-to-person transfers nationally, known as deemed exports.

Finally, the current governance frameworks in the areas of biosecurity and biological weapons regulation do not provide effective control mechanisms for the integration of biotechnology with other emerging technologies. Such control mechanisms, for the integration of biotechnology with AI and AM, should also address the role of research ethics and risk mitigation procedures in related research fields. This would include greater emphasis on raising awareness of potential weapons applications in universities, research institutions, and the DIY community, as well as strengthening industry compliance and due diligence standards. In this context, the current trends of economic statecraft that are focused on industrial policies, trade measures, and new FDI regulations in strategic competition raises the question of how countries can work together on a multilateral basis to address the external consequences of such policies. There is a need to discuss the possibility of developing one or more global governance frameworks to address economic statecraft in strategic competition.

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**Controlling the Transfer of Biotechnology in  
the Age of Strategic Competition**

<Abstract>

Kiwako Tanaka

This paper examines how countries are attempting to ensure strategic priority with regard to biotechnology, a key element in the era of strategic competition, and the impact of these efforts on the nonproliferation of biological weapons. In recent years, rapidly developing technologies in the life sciences have been classified as emerging technologies. While they contribute to the development of the medical and biotechnology industries, they also possess a dual-use nature which can have destructive effects on economic and social activities, as well as the environment if the same technologies are intentionally misused. In addition to the risk of misusing the technology itself, such technologies are also linked to the concern that public disclosure of the technology and research results could educate and empower malicious actors. Furthermore, the convergence of such research in the life sciences with other emerging technologies, particularly artificial intelligence (AI) and additive manufacturing (AM), poses serious challenges to biological weapons control and biosecurity. These innovations are primarily driven by the private sector, making it difficult for governments to manage them. Most of these emerging technologies are transferred in intangible forms such as knowledge or digital information. This makes the management of funds for R&D or controlling intangible technology transfer an important issue.

The management of such biotechnology, coupled with the management of technology in the strategic competition triggered by China's rapid economic and military rise, has become a major policy agenda of economic statecraft for many states in the Global North. The international economic environment since the end

of the Cold War has been one in which free trade is the basic rule, and the focus of export control has been on preventing the proliferation of weapons of mass destruction and their means of delivery through the establishment of multilateral export control regimes. In contrast, in strategic competition, governments increasingly use import and export controls to address supply chain vulnerabilities dealing with foreign components and applications on national security grounds. This paper provides an overview of how the US, China, the EU, and Japan have enacted or amended laws related to emerging technologies to address strategic competition. It elucidates how these states are seeking to manage intangible technology transfers in addition to their existing export controls that focus on goods, through the control of foreign direct investment and strengthening the control of person-to-person transfers nationally, known as deemed exports.

The paper also argues that the current governance frameworks in the areas of biosecurity and biological weapons regulation do not provide effective control mechanisms for the integration of biotechnology with other emerging technologies, particularly AI and AM. For such mechanisms, it should be required to integrate the consideration of the role of research ethics and risk mitigation procedures in related research fields, as challenges are in the intangible technology transfer. This would include greater emphasis on raising awareness of potential weapons applications in universities, research institutions, and the DIY community, as well as strengthening industry compliance and due diligence standards. In conclusion, the paper suggests that there is a need to discuss the possibility of developing one or more global governance frameworks to address economic statecraft in strategic competition, while also taking into account the effective non-proliferation aspects. In this context, the current trends of economic statecraft that are focused on industrial policies, trade measures, and new FDI regulations in strategic competition, raise the question of how countries can work together on a multilateral basis to address the external consequences of such policies.