CIGI Papers No. 249 – March 2021

Biotechnology and Security Threats National Responses and Prospects for International Cooperation

Hanzhi Yu and Yang Xue



CIGI Papers No. 249 – March 2021

Biotechnology and Security Threats

National Responses and Prospects for International Cooperation

Hanzhi Yu and Yang Xue

About CIGI

The Centre for International Governance Innovation (CIGI) is an independent, non-partisan think tank whose peer-reviewed research and trusted analysis influence policy makers to innovate. Our global network of multidisciplinary researchers and strategic partnerships provide policy solutions for the digital era with one goal: to improve people's lives everywhere. Headquartered in Waterloo, Canada, CIGI has received support from the Government of Canada, the Government of Ontario and founder Jim Balsillie.

À propos du CIGI

Le Centre pour l'innovation dans la gouvernance internationale (CIGI) est un groupe de réflexion indépendant et non partisan dont les recherches évaluées par des pairs et les analyses fiables incitent les décideurs à innover. Grâce à son réseau mondial de chercheurs pluridisciplinaires et de partenariats stratégiques, le CIGI offre des solutions politiques adaptées à l'ère numérique dans le seul but d'améliorer la vie des gens du monde entier. Le CIGI, dont le siège se trouve à Waterloo, au Canada, bénéficie du soutien du gouvernement du Canada, du gouvernement de l'Ontario et de son fondateur, Jim Balsillie.

Credits

Managing Director of Digital Economy Robert Fay Senior Publications Editor Jennifer Goyder Publications Editor Susan Bubak Graphic Designer Brooklynn Schwartz

Copyright © 2021 by the Centre for International Governance Innovation

The opinions expressed in this publication are those of the authors and do not necessarily reflect the views of the Centre for International Governance Innovation or its Board of Directors.

For publications enquiries, please contact publications@cigionline.org.



This work is licensed under a Creative Commons Attribution — Non-commercial — No Derivatives License. To view this license, visit (www.creativecommons.org/licenses/by-nc-nd/3.0/). For re-use or distribution, please include this copyright notice.

Printed in Canada on Forest Stewardship Council® certified paper containing 100% post-consumer fibre.

Centre for International Governance Innovation and CIGI are registered trademarks.

67 Erb Street West Waterloo, ON, Canada N2L 6C2 www.cigionline.org

Table of Contents

- vi About the Authors
- 1 Executive Summary
- 1 Biosecurity Threats
- 2 National Regulatory Updates
- 4 Common Challenges Faced by Countries in Response to the Security Threats
- 5 Prospects for Tough but Necessary Global Collaboration
- 8 Taking Advantage of the "Window of Opportunity" for Global Collaboration
- 9 Works Cited

About the Authors

Hanzhi Yu is a CIGI senior fellow and a research fellow in the Department of Political Science, School of Public Affairs, at Zhejiang University, China. Hanzhi holds a Ph.D. in public management from Tsinghua University.

Hanzhi's research field is global governance and global public policy, with a particular focus on global governance for emerging technologies, global private governance and global publicprivate partnership. Her recent publications have appeared in leading journals such as *Global Governance, Sustainable Development* and *Social Sciences in China*, among others. She has written a book on the evolution of the regime complex in global governance (published in Chinese by China Social Sciences Press, 2020).

Hanzhi's current research projects include global governance for emerging biotechnologies, Chinese high-tech companies' engagement in global governance and global public-private partnership in global health governance.

Hanzhi also serves as an adjunct research fellow with the Center for Industrial Development and Environmental Governance of Tsinghua University and as an individual member of the Global Alliance for Genomes and Health.

Yang Xue is a senior fellow at the Center for Biosafety Research and Strategy and an associate professor at the Law School, Tianjin University, China. Yang holds a Ph.D. in management from Tianjin University.

Yang's research field is biosafety/biosecurity governance and regulation, with a particular focus on managing the risks of emerging biotechnology. His recent publications have appeared in leading journals such as the Journal of International Security Studies and Chinese Social Science Digest, among others. In 2020, the results of his biosecurity governance research received the 8th Outstanding Achievement Award of Scientific Research in Colleges and Universities of the Ministry of Education (Youth Achievement Award), the top award in social science research in China.

As a member of the drafting expert group of the Chinese Ministry of Science and Technology, Yang participated in the drafting of the Measures for the Safety Management of Biotechnology Research and Development, the Regulations on the Management of Human Genetic Resources and the Biosafety Law in China.

Yang also participated in the writing of the "Proposal for the Development of a Model Code of Conduct for Biological Scientists" by the delegation of China and Pakistan (BWC/CONF.VIII/WP.30) for the Eighth Review Conference of the Biological Weapons Convention (BWC). In addition, Yang took part in the Meetings of Experts (MX2) for the Eighth BWC Review Conference in 2016–2020.

vi

Executive Summary

Cutting-edge biotechnology, mainly consisting of gene editing, gene drives and gene synthesis, is developing and changing rapidly. It acts as a double-edged sword, bringing benefits to human development in many fields, such as medical treatment and agriculture, while also posing serious threats to biological security, human existence and development. For example, the case of He Jiankui, a young scholar from the Southern University of Science and Technology of China who created gene-edited babies, triggered a global controversy and debate on biosafety in the winter of 2018. This paper argues that the problems China faces do not only exist in China — they are in fact common problems faced by all countries in the world. Of greatest concern is how governments make use of the constructive wisdom contained in "foster strengths and avoid weaknesses," learn from each other, lead and promote the overall planning of the relationship between the "safety and development" of biotechnology in the world, and make contributions to the development of modern global biosafety governance.

Biosecurity Threats

The potential security threats posed by cutting-edge biotechnology can be roughly divided into two categories. The first category is the unintentional erroneous use of biotechnology due to objective factors (Liang et al. 2019), including negative effects caused by technical defects, especially dangers caused by the failure to strictly validate the safety and efficacy of biotechnology before its application to human clinical practice (Maslove et al. 2009), and serious consequences to social security and human health caused by biological laboratory accidents, including biological safety accidents resulting from the intentional release of DIY or genetically modified organisms to the environment in laboratory tests, intermediate tests, environmental release or production tests (Lavery et al. 2010). The second category refers to the security threats caused by subjective technology abuse with intent to cause harm to society, resulting in bioterrorism activities or biological warfare.

Gene Editing

Thanks to CRISPR (clustered regularly interspaced short palindromic repeats), a new gene-editing technology, genetic modification has developed rapidly worldwide in recent years. The precise shearing of specific gene fragments has been achieved, and it will have broad application prospects in disease treatment, genetic breeding and bioengineering (Patrão Neves and Druml 2017). Genetic modification is applied in four main fields. First, it is used for gene function research, in which single or multiple target genes are knocked out or in (Unckless, Clark and Messer 2017). Second, it is used for gene therapy, in which incorrect DNA sequences are corrected at the gene level via gene editing to completely cure genetic diseases (Noble et al. 2017). Third, it is used for gene regulation, in which CRISPR interference is used to reversibly inhibit the expression of target genes without changing the DNA sequences (Hsu, Lander and Zhang 2014). Fourth, it is used for biological defence, in which the genes of invasive species and their vector species are modified to resist sudden threats from large-scale species invasions (Hottes, Rusek and Sharples 2011).

However, genetic modification poses the following significant technical and security risks. First, as its safety and efficacy cannot be fully guaranteed at present, mutations could be produced due to gene editing at target DNA sites, i.e., off-target effects. Second, the actions of smuggling and carrying dual-use equipment containing pathogenic microbial strains and organisms can be easily concealed due to low technical barriers, low cost and easy operation. Third, as the latest geneediting technology can be used to achieve major changes in the biological properties of pathogens, animals, plants and even humans in a short time without leaving any trace, it has become more difficult to identify whether organisms have undergone genome editing. Fourth, innovative applications of the technology have become more extensive in the military field. The US military has developed new weapons and equipment, including biological weapons and "super soldiers" with a new concept of neurological types (RT 2018).

Gene Drives

Gene drives are a technology that can change the reproductive capability of certain species by stimulating the inheritance biases of specific genes, thus causing major changes in population size (Oye et al. 2014). They have a wide range of potential applications, such as cutting off the transmission routes of infectious diseases associated with insects and mice and other rodent populations by modifying their genes, and the prevention and control of crop pests in agriculture by reducing their resistance to pesticides.

However, the technical risks gene drives pose should not be taken lightly. In theory, they can be used to reduce human reproductive capacity and change the number of specific human populations (Esvelt and Gemmell 2017). They may also be used to create insect "weapons," which could be used to spread diseases such as dengue fever and the Zika virus across borders. In recent years, biologists in developed countries, such as the United States and some countries in Europe, have repeatedly advised appropriate biosafety precautions to minimize the uncertain risks that gene drive technology poses to the environment, animals, plants and human health (National Academies of Sciences, Engineering, and Medicine 2016).

Gene Synthesis

Synthetic biology refers to the systematic use of engineering methods and purposeful involvement of artificial life systems - that is, "bottom-up" construction of "minimal genomes" or "artificial genomes" (Bhutkar 2005). Gene synthesis has broad application prospects in medicine. The transformation of human cells, bacteria and viruses can enable the artificially designed organisms to sense disease-specific or artificial signals, target specific abnormal cells and areas of focus, express reporter molecules or release therapeutic drugs, helping us physiologically monitor, diagnose and treat diseases (Bügl et al. 2007). With advantages in intelligence, complexity, safety and controllability, artificial life will improve the diagnosis, treatment and prevention of chronic diseases such as cancer, metabolic diseases and drug-resistant bacterial infections (Sankar and Cho 2015).

However, gene synthesis poses a great threat to biological security. The use of genome modification and DNA fragment assembly can increase and enhance the transfer elements of virus infections in the host genes based on the original virus sequence, or form new viruses with high lethality, high infectivity and the ability to infect a wider range of hosts with additional antibiotic resistance genes (Church et al. 2014). Gene synthesis can artificially design gene sequences of poliovirus and variola virus to synthesize highly pathogenic bacteria and viruses. Extinct pathogenic viruses, such as the 1918 influenza virus, equine poxvirus and ϕ X174 bacteriophage, have been revived, causing the risk of biological terrorism or biowarfare. In addition, artificially modified organisms generally have survival advantages over ordinary organisms. In case of escape, they may proliferate indefinitely in the absence of restrictions, which could destroy the natural ecological balance and cause irreparable loss of biodiversity (Heavey 2018).

In short, the cutting-edge biotechnologies mentioned above have broad application prospects but may pose increasing security risks. Their development without restriction may benefit humankind while also destroying human existence and social order.

National Regulatory Updates

Regulatory Updates in the Global North

In the face of increasing security threats from cutting-edge biotechnology, many countries are constantly updating their regulatory policy systems. Developed countries such as the United States and the United Kingdom are taking the lead in this respect. In September 2011, scientists in the United States and the Netherlands published research on the genetic modification of the highly pathogenic avian influenza virus (H5N1), which caused widespread controversy. Later, the United States issued a number of regulations, including the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (2012), the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (2013) and the National Biodefense Strategy (2018).

In response to increased European terrorism and criminal terrorism cases involving illegal ricin¹ trade in recent years, the UK government

1 Ricin is a natural, highly toxic compound that is a by-product of processing castor beans.

has introduced a series of regulatory policies on cutting-edge biotechnology since 2018, including the UK Biological Security Strategy and Tackling Antimicrobial Resistance 2019–2024: The UK's Five-year National Action Plan.

Regulatory Updates in the Global South: Take China as an Example

In addition to the national regulatory updates in countries in the Global North, countries in the Global South, such as China, are also making efforts to upgrade their regulatory and law system with regard to biotech threats. Over the past 20 years, China has promulgated dozens of laws and regulations concerning pathogenic micro-organisms, biotechnology development and applications, protection of human genetic and biological resources, ethical management, and control of dual-use items and technologies.

The First Round of Biotechnology Safety Legislation in China

The first round of important work on China's biotechnology safety legislation began in the 1990s. In 1993, the Measures for the Safety Management of Genetic Engineering was introduced, which applies to all genetic engineering work, including experimental research, intermediate experiments, industrial production and genetic engineering release. In 1999, after participating in the pilot project of the United Nations Environment Programme, the National Biosafety Framework of China was published. In 2001, the State Council released the Regulations on Administration of Agricultural Genetically Modified Organisms Safety. The agricultural transgenic administrative department then issued a series of management measures and technical standards on genetically modified organisms, involving the safety assessment of genetically modified organisms, the imports of genetically modified organisms, and the identification of transgenic organisms and genetically modified organisms. China's biotechnology safety regulatory system was generally formed at this point and it has been in use up to now.

The Second Round of Biotechnology Safety Legislation in China

After the outbreak of severe acute respiratory syndrome (SARS) in 2003, China ushered in the second round of legislative work. According to statistics, only five years after the SARS epidemic, China had promulgated 36 laws and regulations to strengthen the supervision of biosafety (China National Center for Biotechnology Development 2019, 383). Since then, nearly 30 laws and regulations have been issued or updated, covering the areas of laboratory biosafety, pathogenic micro-organisms, genetic engineering and transgene, protection of human genetic resources and biological resources, ethical management, dual-use items and technical control (ibid.).

The Third Round of Legislation in China

Although China has released numerous laws and regulations related to biological security since the second round of national legislation efforts, they are generally at a low level, and mainly focus on administrative regulations of the competent departments of the State Council, including methods, principles, guidelines and documents. There is still a lack of upper-level laws for programmatic purposes. In particular, the case of genetically modified babies produced by He Jiankui and the outbreak of the coronavirus disease 2019 (COVID-19) pandemic has further accelerated the progress of this legislation.

The Biosecurity Law of the People's Republic of China was adopted on October 17, 2020, and will come into force on April 15, 2021. As a programmatic law, it puts forward a series of principles on biotechnology development and regulation. The first principle relates to risk prevention. It makes all units engaged in biotechnology research, development and application responsible for the security of their own biotechnology research, development and application, and requires them to take risk-control measures; formulate training procedures, guidelines for follow-up inspection and regular reporting systems; and strengthen process management.

The second principle is hierarchical management and control. This is a management strategy to address biological security threats by level. Biotechnology research and development (R&D) is divided into three risk levels (high, medium and low) based on the degree of potential harm to public health, industry, agriculture and the environment. The grading standards and directories will be formulated, adjusted and published by competent science and technology departments. In particular, highand medium-risk biotechnology R&D must

be carried out by corporations established in China according to law, and corresponding recording systems will be implemented.

The third principle concerns risk assessment. It requires the risk assessment of high- and medium-risk biotechnology R&D. Risk control and biosecurity emergency plans must be formulated to reduce the implementation risks of R&D.

The fourth principle relates to ethical review. Clinical research on new biomedical technologies must be ethically reviewed, and the research must be conducted by medical institutions with corresponding qualifications. Human clinical research operations must be performed by qualified health professionals.

The fifth principle involves dynamic regulation, reflecting the difficulty and particularity of biosecurity management. It requires the regulation department to implement a division of labour according to responsibilities to track and evaluate biotechnology applications. Biosecurity risks must be assessed in a timely manner, and effective measures must be taken for remedy and control.

In addition, China's National Security Law specifies the implementation of a registration system for the purchase or use of important equipment and special bioagents related to biosecurity. Units engaged in biotechnology research, development or application must register them in accordance with the control list, and report to relevant regulatory departments for recording.

Common Challenges Faced by Countries in Response to the Security Threats

Although countries in the Global North and Global South are working hard to improve their own regulatory systems to defend against and respond to security threats from cutting-edge biotechnology, they inevitably face many common challenges. First, there are difficulties in coordinating the dual goals of technological development and technological security. It is not easy to maintain a balance between the two. Coordinating these dual goals is a critical test for every country. All countries must take into account the benefits of life science to human health, scientific development and social progress, but must also pay attention to their risks and serious economic and social consequences in case they are used for harmful purposes. They must maintain security and protect the public interest by means of law, as well as encouraging research and industry innovation through policies and laws to ensure the advancement of biotechnology.

Second, legal systems lag behind unknown technological security threats. Currently, as the technological paths and consequences involving the development of cutting-edge biotechnology are still far from certain, the scientific community can only evaluate the security of cutting-edge biotechnology based on the assumption of unknown potential risks. For example, with regard to the human embryo studies using CRISPR gene-editing technology, scientists admit that the tool can cause large DNA deletions and rearrangements near its target site on the genome; the risks and consequences of unwanted DNA changes are unknown (Ledford 2018). Even if a cutting-edge biotechnology has been fully discussed and undergone risk assessment in the scientific community, the threats and risks it may present to humanity are still unknown. Therefore, effective resolution of judicial disputes cannot be implemented due to the lack of necessary judicial determination of causality, which can lead to unscrupulous research misconduct in breach of "red lines." The case of the gene therapy death of a patient in Illinois, United States, in 2007 (Wadman 2007); a criminal lawsuit for online trafficking of ricin in the United Kingdom in 2016 (United States of America 2016); and the genetically modified baby incident of He Jiankui in China in 2018 (Cyranoski 2019) have sent worrying signals: regulation based solely on the actions of government in specific countries may not be as effective in punishing illegal applications of cutting-edge biotechnology as expected.

Third, there is a dilemma between regulatory demand for multi-sector cooperation and division of authority. The particularity of biotechnology means that its security regulation needs to be coordinated by multiple departments, which inevitably involves division of authority and responsibility between regulators. The regulatory

agencies currently associated with biosecurity in the United States include the National Institutes of Health, the Department of Agriculture, the Environmental Protection Agency, the Food and Drug Administration, and the Occupational Safety and Health Administration. These agencies have issued many regulations, standards and guidelines. In addition, the United States has established coordinating agencies such as the Institutional Biosafety Committee, the Recombinant DNA Advisory Committee, the National Science Advisory Board for Biosecurity, and the Office of Science and Technology Policy. However, how to scientifically and reasonably establish the division of powers among the regulatory agencies and ensure the effectiveness of enforcement are still problems that trouble the US government. In particular, the National Science Advisory Board for Biosecurity triggered the issue of power conflicts among the US supervision departments by first reporting "the study of new infectious functions of avian influenza" (Palmer, Fukuyama and Relman 2015). In China, the departments associated with the security regulation of cuttingedge biotechnology include the Ministry of Science and Technology, the National Health Commission, the Ministry of Agriculture and Rural Affairs, the Ministry of Ecological Environment, and the State Food and Drug Administration. Scientific and reasonable determination of division of authority between regulators to ensure the effectiveness of their cooperation and enforcement is a common issue with regard to the regulation of cutting-edge biotechnology.

Fourth, multi-stakeholder engagement in policy making needs further strengthening. The development of democratic review mechanisms for stakeholders such as biologists, sociologists, industry, the media and the public is also testing the management wisdom of decision makers in various countries. Stakeholders have different understandings of cutting-edge biotechnology and its security and have different requirements. For example, experts in the social sciences who participate in the formulation of relevant government laws and policies often provide advice on the basis of their expertise in law, ethics, economics, public management, risk prevention and control, and so on. However, sociologists are less likely to have corresponding biological expertise and experience in biosafety regulation, and may formulate policies only from their professional perspective, resulting

in poorly targeted policies and regulations, as well as disconnection from front-line research. Biologists often reject and resist regulatory measures from beyond their own professional fields and tend to formulate industry regulations by themselves. This tendency has been reflected in international meetings from the Asilomar Conference in 1975 to the International Summit on Human Gene Editing in 2018. Fierce disputes emerged among experts and scholars in different fields. In addition, public participation in cuttingedge biotechnology regulation has received wide attention. It should also be noted that the construction of such a democratic deliberation mechanism, which includes stakeholders such as biologists, sociologists, the public and enterprises, must also take into account the different social and cultural backgrounds of China and the United States, and will test the management wisdom of the two governments.

Prospects for Tough but Necessary Global Collaboration

While there are common challenges in dealing with emerging biosafety threats within countries, the greater challenge lies in the fact that the governance concerns caused by emerging biosafety threats are often transnational and require collaboration among all countries.

The Need for Global Collaboration

There are three characteristics of emerging biotechnology applications that determine the need for global collaboration. First, the security consequences caused by the development of cutting-edge biotechnologies will be borne by all countries, so global governance is essential. In many cases, biosecurity threats affect all of humanity and entire ecosystems, so the consequences are borne by the whole world. From the perspective of time, since current genetic technology is capable of modifying embryos, the consequences of such modification could have long-term influence across generations. From the perspective of space, if genes are maliciously modified and spread widely across the biosphere, highly destructive genetic contamination can occur. What is worse, such genetic contamination is difficult to contain within a country or region in the current global environment and could destroy the earth's ecological balance and cause a global ecological crisis. Therefore, whether from the perspective of time or space, security threats caused by the development of cutting-edge biotechnology are a real global governance issue that should attract the attention of all countries.

Second, as cutting-edge biotechnology is becoming widespread, and national regulation is constrained by the Cannikin law,² stronger cooperation and consensus at the international level is urgently required. At present, technologies including gene editing and biological synthesis have become increasingly commonplace and popular, for the following reasons. First, the difficulty of acquiring cutting-edge biotechnology is decreasing. With the disclosure of key gene sequence information, the key gene sequences of highly pathogenic pathogens and viruses can be easily obtained from academic conferences, journals and public databases. Second, key experimental materials, including gene sequences, can be easily obtained. Biotechnology companies can provide all the technical services and reagents needed for experiments. It is possible for anyone to easily obtain genetic sequences, experimental equipment, consumables and substitutes for highly pathogenic pathogens or viruses online, and the cost is decreasing every year. The popularization of cutting-edge biotechnology enables illegal users to carry out their experiments in countries or regions with weak regulation rather than in those with strong regulation. In view of this Cannikin law effect, building a unified platform at the international level to regulate the development of cuttingedge biotechnology is becoming necessary.

Third, there is a substantial need for international cooperation as the subject of current bioterrorism threats has shifted from state actors to nonstate actors. The main sources of current bioterrorism threats include ethnic separatists, transnational criminal organizations, terrorist or cult organizations, and biohackers (Germany 2016). Actions by these actors are concealed, with a strong degree of research freedom, making them difficult to investigate and regulate, and they already have application capabilities using typical dual-use technologies such as gene-editing platforms. For instance, at the Eighth Review Conference of the Biological Weapons Convention, the US government specifically cited the successive defeats of bioterrorism conspiracies reported by Kenya and Morocco, as well as more than 15 criminal cases involving biological weapons in the United States in the past decade. The United States expressed concern about non-state actors engaging in bioterrorism and emphasized the severity and urgency of preventing bioterrorism on a global scale (United States of America 2016).

The Tough Situation of Global Collaboration

At present, the main platform for international cooperation in the field of biosecurity lies in the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (Biological Weapons Convention, or BWC, for short). The BWC draft was jointly proposed by 12 countries (including the United States, the United Kingdom and the former Soviet Union) to the United Nations General Assembly in 1971 and came into force in 1975. The main contents of the BWC are as follows: under no circumstances shall states parties develop, produce, store or acquire microbial preparations, toxins or weapons other than for peaceful purposes; nor shall they assist, encourage or guide other countries to acquire such microbial preparations, toxins and weapons; states parties shall destroy all microbial preparations, toxins and weapons within nine months after the entry into force of the convention; and states parties may file a complaint with the UN Security Council on the violation of the convention by other countries.3

The BWC has no international agency, governing council or permanent secretariat. States parties meet for a review conference every five years. The conference agenda is established by article XII of the convention: the operation of the convention, with a view to assuring that its purposes and provisions are being realized; relevant developments in science and technology;

² According to the Cannikin law, the shortest board in a wooden bucket will determine the amount of water it can hold. In order to increase the bucket's capacity, you must find the shortest board and improve it.

³ See www.un.org/disarmament/biological-weapons.

and progress on chemical disarmament. A total of eight review conferences have taken place since the first one in 1980. The purpose of these conferences is to "ensure that the Convention remains relevant and effective, despite the changes in science and technology, politics and security since it entered into force."⁴

It needs to be recognized that through the efforts under the BWC framework, the world has successfully established the near universal norms against the use of biological weapons (Cross and Klotz 2020). However, practical problems faced by the BWC in dealing with the current security threats of emerging biotechnology cannot be ignored.

The most prominent problem is that the BWC has difficulties in forming a verification mechanism with consensus among all parties. According to article XII of the BWC, states parties shall review and monitor the implementation of the convention through a review conference held every five years. However, as the mandatory verification mechanism involves core interests of national security, it has been difficult for states parties to reach a consensus in the negotiation of the BWC's verification protocol. In 2001, the unilateral withdrawal of the United States in the negotiation of the verification protocol forced it to rely on the annual expert group meetings and the meetings of states parties to review the implementation of the convention. Since prior to the Seventh Review Conference in 2011, states parties have been exploring options to voluntarily enhance transparency and the exchange of information, experiences and best practices on national implementation, in bilateral, multilateral and regional formats. Examples of such initiatives include some developed countries conducting a pilot "peer review" exercise and jointly presenting a paper on a compliance assessment pilot project. But the developing countries represented by the non-aligned movement generally hold the attitude of concern and doubt, especially in the background of the widening gap in biotechnology between two sides — it is impossible for the developing countries with technical weakness to send scientific and technical personnel with equivalent capability to participate in it.

At the same time, since non-state actors have become an important source of emerging biotechnology threats, the framework of the BWC

also tries to deal with such a situation but has not vet produced results accepted by all parties. In 2002, the Fifth Review Conference of the States Parties to the BWC proposed for the first time the suggestion of "the content, promulgation and application of the code of conduct for biological scientists" (Fifth Review Conference of the States Parties 2002). Since then, some states parties have successively put forward working papers on a code of conduct for non-state parties. For example, at the Eighth Review Conference in 2016, China and Pakistan jointly submitted a working paper, "Proposal for the Development of a Model Code of Conduct for Biological Scientists under the Biological Weapons Convention," aimed at improving the biosafety awareness of researchers from the aspects of the establishment of scientific research projects, the dissemination of achievements, the popularization of science and technology, international communication, and so on. However, so far, the states parties have not reached a consensus on any "code of conduct" for non-governmental subjects. In addition to the BWC's framework, several international governance institutions are also partly engaged with global biosecurity governance. In the issue area of arms control, the Geneva Protocol was established in 1925 with the purpose of preventing the use of biological or chemical weapons in war, but this protocol was adopted long before the revolution of modern biotechnology. Another case is the Environmental Modification (ENMOD) Convention adopted in 1976, with its aim to prevent the use of certain techniques, at certain degrees, to modify the environment for warfare or other hostile use. However, the ENMOD Convention is far less influential, with less than half the membership of the BWC. Additionally, the World Health Organization has established relevant guidelines, such as the Laboratory Biosafety Manual, Biorisk Management: Laboratory Biosecurity Guidance and Guidance on Regulations for the Transport of Infectious Substances, but all of these guidelines are engaged voluntarily without any binding force (Rhodes 2010).

Meanwhile, the current global governance platforms dominated by some non-state subjects also attempt to build self-regulation for the industry. One example is that, with regard to the development of human genome editing, more than 60 guidelines have been released by various scientific organizations around the world in the past five to six years. Another example is

⁴ Ibid.

that, in the field of synthetic biology, industry associations, including the Industry Association of Synthetic Biology and the International Gene Synthesis Consortium, have formulated codes of conduct for their member companies. However, the problem of self-regulation lies in that it does not have mandatory binding force, and its binding effect on actors remains to be tested.

Taking Advantage of the "Window of Opportunity" for Global Collaboration

Although the negotiations and agreement on a protocol that includes a verification mechanism and that is legally binding for the purpose of comprehensively strengthening the BWC have reached a deadlock, there is reason for optimism and a chance to acknowledge that there is a "window of opportunity" for global collaboration to deal with biosecurity threats.

First, due to the COVID-19 pandemic, the world is paying close attention to global health governance and biosafety issues, which will play a significant role in building consensus on global governance. As UN Secretary-General António Guterres (2020) has warned, "the weaknesses and lack of preparedness exposed by this pandemic provide a window onto how a bioterrorist attack might unfold — and may increase its risks. Non-state groups could gain access to virulent strains that could pose similar devastation to societies around the globe."

Second, despite the diverse changes in the international political situation, addressing and responding to common global governance challenges is becoming a priority for many governments around the world. To this end, the recent return of the US government to the multilateral global governance platforms under US President Joe Biden is a positive step. Meanwhile, Chinese President Xi Jinping also called for strengthened global cooperation in his special address for the 2021 World Economic Forum, remarking that "we have been shown time and again that to beggar thy neighbor, to go it alone, and to slip into arrogant isolation will always fail. Let us all join hands and let multilateralism light our way toward a community with a shared future for mankind" (Xi 2021).

Third, the Ninth Review Conference of the BWC will be held in late 2021, and all parties have the chance to take advantage of this opportunity to make breakthroughs in cooperation agendas. The previous review conferences have been criticized for a number of reasons, including that the one-week schedule is too short to discuss issues in sufficient depth (Sims 2011), and that conferences have never successfully reviewed scientific and technological developments relevant to the convention (Dando 2016). It is expected that this year's conference could address these issues as virtual conferences could have a more flexible schedule.

Global leaders should take advantage of the current window of opportunity for global collaboration and to ensure advancements in biotechnology can benefit human development.

Works Cited

- Bhutkar, Arjun. 2005. "Synthetic Biology: Navigating the Challenges Ahead." Journal of Biolaw and Business 8 (2): 19–29. https://pubmed.ncbi.nlm.nih.gov/16538811/.
- Bügl, Hans, John P. Danner, Robert J. Molinari, John T. Mulligan, Han-Oh Park, David A. Roth, Ralf Wagner, Bruce Budowle, Robert M. Scripp, Jenifer A. L. Smith, Scott J. Steele, George Church and Drew Endy. 2007. "DNA Synthesis and Biological Security." Nature Biotechnology 4 (25): 627–29. doi:10.1038/nbt0607-627.
- China National Center for Biotechnology Development. 2019. Collection of Biosafety Related Laws and Regulations of the People's Republic of China. Beijing, China: Science and Technology Literature Press.
- Church, George, Michael Elowitz, Christina Smolke, Christopher Voigt and Ron Weiss. 2014. "Realizing the Potential of Synthetic Biology." Nature Reviews Molecular Cell Biology 6 (15): 289–94. doi:10.1038/nrm3767.
- Cross, Glenn and Lynn Klotz. 2020. "Twenty-first century perspectives on the Biological Weapon Convention: Continued relevance or toothless paper tiger." Bulletin of the Atomic Scientists 76 (4): 185–91. doi:0.1080/00963402.2020.1778365.
- Cyranoski, David. 2019. "The CRISPR-baby scandal: what's next for human gene-editing." Nature 566: 440–42. doi:10.1038/d41586-019-00673-1.
- Dando, Malcolm. 2016. "Find the time to discuss new bioweapons: the Biological Weapons Convention needs to take the assessment of emerging scientific dangers more seriously, argues Malcolm Dando." Nature 535 (7610): 9.
- Esvelt, Kevin M. and J. Neil Gemmell. 2017. "Conservation Demands Safe Gene Drive." *PLOS Biology* 15 (11): e2003850. https://journals.plos.org/plosbiology/ article?id=10.1371/journal.pbio.2003850.
- Fifth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction. 2002. "Final Document." BWC/CONF.V/17. Geneva, Switzerland: United Nations. https://undocs.org/BWC/CONF.V/17.
- Germany. 2016. "Strengthening Confidence-building Measures in Regard to Dual Use Materials." United Nations Preparatory Committee for the Eighth Review Conference. BWC/CONF.VIII/PC/WP.35, August 16.

- Guterres, António. 2020. "Secretary-General's remarks to the Security Council on the COVID-19 Pandemic." April 9. www.un.org/sg/ en/content/sg/statement/2020-04-09/secretary-generalsremarks-the-security-council-the-covid-19-pandemic-delivered.
- Heavey, Patrick. 2018. "Synthetic Biology Ethics: A Deontological Assessment." *Bioethics* 27 (1): 442–52. doi:10.1111/bioe.12052.
- Hottes, Alison, Benjamin Rusek and Fran Sharples, eds. 2011. Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories, 133–36. Washington, DC: National Academies Press.
- Hsu, Patrick, Eric S. Lander and Feng Zhang. 2014. "Development and Applications of CRISPR-Cas9 for Genome Engineering." Cell 157 (6): 1262–78. doi:10.1016/j.cell.2014.05.010.
- Lavery, James, Paulina Tinadana, Thomas Scott, Laura Harrington, Janine Ramsey, Claudia Ytuarte-Nuñez and Anthony James. 2010. "Towards a Framework for Community Engagement in Global Health Research." Trends in Parasitology 26 (6): 279–83. doi:10.1016/j.pt.2010.02.009.
- Ledford, Heidi. 2018. "CRISPR gene editing produces unwanted DNA deletions." Nature, July 16. doi:10.1038/d41586-018-05736-3.
- Liang, Huigang, Xiaowei Xiang, Haixia Ma and Zhiming Yuan. 2019. "History of and Suggestions for China's Biosafety Legislation." Journal of Biosafety and Biosecurity 1 (2): 134–39. www.sciencedirect.com/science/article/ pii/S2588933819300342.
- Maslove, David, Anisa Mnyusiwalla, Edward Mills, Jessie McGowan, Amir Attaran and Kumanan Wilson. 2009. "Barriers to the Effective Treatment and Prevention of Malaria in Africa: A Systematic Review of Qualitative Studies." BMC International Health and Human Rights 9 (1). doi:10.1186/1472-698X-9-26.
- National Academies of Sciences, Engineering, and Medicine. 2016. Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values. Washington, DC: National Academies of Sciences, Engineering, and Medicine.
- Noble, Charleston, Jason Olejarz, Kevin Esvelt, George Church and Martin Nowak. 2017. "Evolutionary Dynamics of CRISPR Gene Drives." Science Adventure 3 (4): e1601964. doi:10.1126/sciadv.1601964.
- Oye, Kenneth A., Kevin Esvelt, Evan Appleton, Flaminia Catteruccia, George Church, Todd Kuiken, Shlomiya Bar-Yam Lightfoot, Julie McNamara, Andrea Smidler and James P. Collins. 2014. "Regulating Gene Drives." Science 345 (6197): 626–28. doi:10.1126/science.1254287.

Palmer, Megan J., Francis Fukuyama and David A. Relman. 2015. "A more systematic approach to biological risk." Science 350 (6267): 1471–73. https://science. sciencemag.org/content/350/6267/1471.

- Patrão Neves, Maria and Christiane Druml. 2017. "Ethical Implications of Fighting Malaria with CRISPR/Cas9." BMJ Global Health 3: 1–2. doi:10.1136/bmjgh-2017-000396.
- Rhodes, Catherine. 2010. International Governance of Biotechnology: Needs, Problems and Potential. New York, NY: Bloomsbury Academic.
- RT. 2018. "Could science-fiction super soldiers become reality after extreme US military tests?" RT, August 18. www.rt.com/ usa/436277-experiment-super-soldier-military/).
- Sankar, Pamela and Mildred K. Cho. 2015. "Engineering Values into Genetic Engineering: A Proposed Analytic Framework for Scientific Social Responsibility." American Journal of Bioethics 15 (12): 18–24. doi:10.1080/15265161.2015.1104169.
- Sims, Nicholas A. 2011. "A simple treaty, a complex fulfillment: A short history of the Biological Weapons Convention Review Conferences." Bulletin of the Atomic Scientists 67 (3): 8–15. https://doi.org/10.1177/0096340211407400.
- Unckless, Robert, Andrew Clark and Philipp Messer. 2017. "Evolution of Resistance against CRISPR/Cas9 Gene Drive." Genetics 205 (2): 827–41. doi:10.1534/genetics.116.197285.
- United States of America. 2016. "Acquisition and use of biological and toxin weapons: addressing the threat." BWC/CONF.VIII/WP.19. November.
- Wadman, Meredith. 2007. "Gene therapy might not have caused patient's death." Nature 449 (7160): 270. www.nature.com/ news/nature/journal/v449/n7160/pdf/449270c.pdf.
- Xi, Jinping. 2021. "Special Address by Xi Jinping, President of the People's Republic of China." World Economic Forum, January 25. www.weforum.org/events/the-davosagenda-2021/?stream=day-one-davos-agenda&streamitem=coming-up-special-address-by-xi-jinping-presidentof-the-peoples-republic-of-china#stream-header.

Centre for International Governance Innovation

67 Erb Street West Waterloo, ON, Canada N2L 6C2 www.cigionline.org

♥ @cigionline

