China's Biosafety/Biosecurity Concept and Governance System

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Abstract: In the process of responding to governance crises and challenges due to various biosafety and biosecurity risk factors locally and abroad, China has gradually established and improved its biosafety/biosecurity concept and governance system. This article summarizes the formation and development of the biosafety/biosecurity concept with Chinese characteristics by analyzing the evolution of China's cognition of biosafety/biosecurity risks. Under the guidance of the Chinese biosafety/biosecurity concept, the country has formed a governance system guided by national strategy and coordinated by the rule of law, system, and management. The modernization level of the biosafety/biosecurity governance system and governance capabilities has been significantly improved. Compared with international practice, China's national biosafety/biosecurity concept and governance system pay increased attention to inclusive overall planning, preventive governance, diversified governance, and international cooperation. It provides Chinese wisdom and solutions for promoting global biosafety/biosecurity governance and building a community of shared future for human biosafety/biosecurity.

Keywords: China, national biosafety/biosecurity concept, biosafety/biosecurity governance

Biosafety/biosecurity risk is a major challenge to governance that mankind needs to address. Biosafety/biosecurity governance issues, such as the prevention and control of emerging infectious diseases, supervision

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of biotechnology safety, response to biological weapons and bioterrorism, pathogenic organisms and laboratory biosafety management, continue to emerge. This scenario poses challenges for countries to improve relevant governance concepts, capabilities, and systems. Since the second decade of the 21st century, China's systems of governance for biosafety/biosecurity is substantially progressing, and the modernization level of its biosafety/biosecurity governance capabilities has entered a new historical stage. Especially around 2020, China's emphasis on biosafety/biosecurity governance has significantly increased, and biosecurity has been included in the overall concept of national security, which marks a historic leap in biosecurity governance in China. In 2021, the Political Bureau of the Central Committee of the Party conducted a special research on biosafety/biosecurity issues in collective learning, which is an important sign of the initial formation of the concept and ideology of national biosecurity. In the same year, China promulgated and implemented the Biosecurity Law of the People's Republic of China, which establishes biosafety/biosecurity governance mechanisms and improves its governance institutions. As such, a relatively comprehensive biosafety/biosecurity governance system has been formed.

With the rapid development of biosafety/biosecurity governance in China, the academic community has conducted preliminary theoretical constructions on the relationship between biosafety/biosecurity and national security. It has also summarized the development logic of the biosafety/biosecurity governance of China from different perspectives. However, academic research on the evolution of the concept and system of China's biosafety/biosecurity governance remains insufficient. For example, China has not formulated the context of biosafety/biosecurity with Chinese characteristics, and it has evidently lagged behind the development reality of China's practices in relation to biosafety/biosecurity governance. This article does not seek to present a comprehensive analytical framework for biosafety/biosecurity issues in China. Instead, it relies on historical review and long-term research on practices related to biosafety/biosecurity governance to analyze the evolution process of its perception of biosafety/biosecurity risks and understand the logic of its governance concepts. It summarizes the concept and governance system of biosafety/biosecurity in China, as well as the Chinese characteristics and global

significance of specific practices. In addition, it explains the significance of the concept of a community with a shared future for mankind in understanding China's biosafety/biosecurity governance and its underlying mechanisms. The article preliminarily summarizes and refines the basic structure, content, and characteristics of China's biosafety/biosecurity concept and provides a theoretical basis for follow-up research.

I. Evolution of the Biosafety/Biosecurity Concept

The understanding of biosafety/biosecurity is enriched and perfected with the continuous emergence of social risks and challenges to governance as a result of biotechnology. After nearly 50 years of development, a set of biosafety/biosecurity concept system has been formed in the western context. Biosafety/biosecurity has dovetailed with national security governance, which forms a relatively complete system of strategies, laws, and policies. Based on its practice, China has gradually enriched its knowledge of biosafety/biosecurity risks and developed a related concept with Chinese characteristics.

A.Biosafety/Biosecurity in the Western Context

Biosafety has attracted widespread attention since the emergence of recombinant DNA technology in the 1970s. In 1972, American biologist Herbert Boyer extracted from a restriction endonuclease from *Escherichia coli*, which is capable of cutting DNA strands at specific coding regions, thus enabling recombination between different genetic materials. This achievement has raised concerns among life scientists about future major changes to pathogens, plants and animals, and even human traits, which may be accompanied by the emergence of a number of unprecedented biological traits. To establish a basic framework for the effective management and control of safety risks, biological scientists, policy makers, social science experts, and industry members held the Asilomar Conference in 1975. Based on the consensus of the meeting, the US National Institutes of Health published the world's first regulatory document for biotechnology research entitled "Recombinant DNA Research Guidelines" in 1976. This guideline proposes the concept of *biosafety* for the first time, that is, "a series of measures to enable the safe control of pathogenic microorganisms

in the laboratory."[1]

With the continuous breakthrough of life science technology and the expansion of its application in agriculture, medicine, and other fields, new risks and challenges are constantly emerging, and the concept of biosafety is evolving accordingly. In 1992, the United Nations Environment Programme has developed the Convention on Biological Diversity. In Article 8 of the Convention, the concept of biosecurity is expanded to cover the areas of reducing all potential threats to biological resources, modern biotechnology, and intentional introduction into the environment.[2] In 2000, under the framework of the Convention on Biological Diversity, parties signed the Cartagena Protocol on Biosafety, whose Article 4 states, "apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."[3] In 2004, the World Health Organization released the third edition of the Laboratory Biosafety Manual, which uses *laboratory biosafety* to describe the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins or their accidental release.[4] In the fourth edition in 2021, this concept was updated to "containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release." The main difference is that the target of prevention has been extended from *pathogens and toxins* to biological agents.[5] Thus far, *biosafety* not only includes risks to the ecological environment due to modern biotechnology but also extends to the protection from all threats to human health.

Compared with biosafety, *biosecurity* emerged due to the need to defend against biological weapons. According to the third edition of the Laboratory Biosafety Manual of the World Health Organization, "laboratory biosecurity" refers to institutional and personal security measures designed to prevent the

[1] NIH, "Recombinant DNA Research Guidelines," *Federal Register*, Vol. 41, No. 131, 1976, pp. 27902–27943.

[2] United Nations (1992), Convention on Biological Diversity, https://www.cbd.int/doc/legal/cbd-en.pdf.

[3] Secretariat of the Convention on Biological Diversity (2000), Cartagena Protocol on Biosafety to the Convention on Biological Diversity, https://bch.cbd.int/protocol/text/.

[4] WHO (2004), Laboratory Biosafety Manual, 3rd edition, https://www.who.int/publications/i/item/9241546506.

[5] WHO (2020), Laboratory Biosafety Manual, 4th edition, https://www.who.int/publications/i/item/9789240011311.

loss, theft, misuse, diversion, or intentional release of pathogens and toxins. In 2006, the World Health Organization issued guidelines for laboratory biosecurity, which describe the protection, control, and accountability for valuable biological materials within laboratories, to prevent unauthorized access, loss, theft, misuse, diversion, or intentional release. The Organization for Economic Cooperation and Development defines it as institutional and personal security measures and procedures designed to prevent the loss, theft, misuse, diversion, or intentional release of pathogens or parts of them and toxin-producing organisms, as well as such toxins that are held, transferred, and/or supplied by BRCs (Biological Resource Center). The main difference between biosecurity and biosafety is the restriction of the subjective intentional or unintentional biohazardous behavior of actors.

Since the anthrax mail attacks in 2001, the United States has responded to the direct challenge of biosecurity to national security, including the Biodefense for the 21st Century of the Bush administration, the National Biodefense Strategy of the Trump administration, and the National Biodefense Strategy and Implementation Plan of the Biden administration. These national biosecurity strategies used the term *biodefense*, which refers to a series of national governance measures, including biosafety risk monitoring, emergency response, conventional stockpiling, and social mobilization. Therefore, the concept of biosafety in the western context basically includes biosafety, biosecurity, and biodefense.

B. Evolution of Biosecurity Risk Perception in China

Prior to 2000, biosecurity in China was a security issue in the field of professional technology, which did not reach the level of national governance. After the 21st century, under the impact of biosecurity emergencies, biosecurity issues began to be linked with social stability and human security, and related academic research was published. The initial stage of the relevant research mainly focused on the analysis of biosecurity threats and called for increased attention and investment in the construction of national biosecurity. At the time, biosecurity issues mainly focused on three categories, namely, preventing bioterrorism attacks, fighting against large-scale infectious diseases, and controlling biological weapons. In addition to research on biological weapons arms control, research results have been released on the impact of synthetic

biology, bioinformatics, and the prevention and control of infectious diseases on national security.

With the increasing number of real biosecurity challenges, China's awareness of biosecurity risks is also constantly evolving and improving. A number of interdisciplinary scholars have begun to pay attention to the interrelationship between biosecurity issues and national security and conduct research on the governance of biosecurity crises. Scholars point out that the major challenge is using traditional high-level political governance ideas to address nontraditional security issues. They conduct research on China's establishment of a code of conduct for biological scientists and a multi-level governance system for scientists. They argue about safety governance issues such as risks in different fields of biotechnology, related assessment methods, and foreign regulatory measures. Furthermore, they discuss the major challenges and development trends of global biosecurity governance.

Around 2020, China clearly stated that biosafety/biosecurity is an important component of national security. Biosafety/biosecurity is one of the areas of security in the overall concept of national security, and its governance has been integrated into the national governance system, which marks the basic formation of China's biosafety/biosecurity concept or thinking. The theoretical community is seeing published results of the exploration of the influence of biosafety/biosecurity on national security. China's risk awareness of biosafety/biosecurity has been deepened and expanded at three levels as follows.

The first pertains to a transition from single to systemic risk. The outbreak of SARS in 2003 and the COVID-19 pandemic in late 2019 accelerated China's emphasis on biosafety and the introduction of regulations and policies. Between two large-scale outbreaks, China faced zoonotic diseases, such as H5N1 and H7N9 avian influenza, African swine fever, Ebola, Middle East respiratory syndrome, and food, drug, and vaccine safety crises, since the new century. In the process of addressing emergent incidents of biosafety, the Chinese government and academic circles have realized that the boundaries of biosafety issues tend to be generalized, which displayed increasingly evident spillover effects. Especially since the 1990s, China's life science and technology have rapidly developed, and the dual-use problem of technological development has created a new understanding in China about biosafety risks. In particular, along

with the expansion of applications to health, resources, energy, environment, and other areas, the potential for misuse and abuse of biotechnology has increased, which contributes to a growing awareness of the strategic impact of the imbalance between biotechnology and industrial development.

The second change is from domain to national security. With the growth of China's comprehensive national strength and the improvement of daily living, people pay more and more attention to life and health. Thus, China has also increased investment in this area, which has promoted the attention of the entire Chinese society to biotechnology safety. This aspect has greatly contributed to China's understanding of the occurrence pattern and hazard level of biosafety/biosecurity risks. Moreover, biosafety/biosecurity risks have become multi-regional and globalized, and their scope has expanded from life and health to economic development, social stability, and strategic interests. Biosafety/biosecurity risks exert an impact on national security and social stability. Traditional governance model lack the institutional system and means for effectively addressing the prevention, control, and recovery of biosafety/biosecurity risks and hazards. Thus, once a biosafety/biosecurity risk point is detonated, it can easily lead to local economic and social turmoil and ecological disasters. For example, the impact of the COVID-19 pandemic has exceeded the field of public health, which resulted in threats to national political, economic, social, and ecological security. As such, it has changed from a single risk to a compound crisis and from a local problem to a global evolution into national security. The COVID-19 pandemic has even triggered a complex crisis of social, economic, and political disorder in certain countries and regions, which led to serious disasters to national development and the lives of the people.

Third, it has evolved from national security to common security. China's traditional concept of international biosafety/biosecurity governance focuses on eliminating biological weapons and export controls on related equipment and technologies. In the process of opening up and integrating into the international community, China's foreign personnel exchanges, trade exchanges, and scientific research cooperation have significantly increased. In addition, biosafety/biosecurity threats from outside has also increased. Therefore, China is increasingly willing to participate in global biosafety/biosecurity governance. Especially after entering the second decade of the 21st century, global biosafety/

biosecurity governance has begun to change. For example, major powers have encountered challenges to global biosafety/biosecurity governance, and their respective domestic political ecology has undermined their willingness to cooperate to seek common security. Instead, these countries have become more willing to fight over the right to formulate biosafety/biosecurity rules and the dominance of investigations of biosafety/biosecurity incidents. At the same time, the international biosafety and biosecurity governance system under the framework of the United Nations, which includes the Biological Weapons Convention and the World Health Organization, has displayed evident shortcomings. Against this background, China realizes that it cannot stand alone in the field of biosecurity; as such, it must promote the construction of a community with a shared future for mankind. The community of human destiny is more prominently reflected in the field of biosafety/biosecurity due to the universality of biosafety/biosecurity risks and the dual-use nature of biotechnology. Therefore, China continues to increase its participation in international governance on biosecurity, increase assistance on foreign biosecurity, advocate and promote a community of a shared future for mankind, and put forward the Global Security Initiative. At the same time, China pays increased attention to the role of soft power, think tanks, and discourse power in international exchanges on biosafety/biosecurity. Through a series of efforts, China becomes a positive factor and a powerful driving force that leads the reform on the global system for biosafety/biosecurity.

II. Chinese Concept and Governance of Biosafety/Biosecurity

A.The Chinese Concept of Biosafety/Biosecurity

China's concept of biosafety/biosecurity originates from a security concept with Chinese characteristics. The meaning of *security* in China is apparently different from that in the west. The Chinese word *anquan* denotes safety and security. This definition is reflected not only in the field of biological security but also in nuclear security, network security, and other fields. This difference in semantics reflects that China's security concept is distinct from that of the west.

On the one hand, China's security concept is relatively richer, extensive,

comprehensive, inclusive, and developmental. Its security governance can prevent and resolve risks and prevent crises, enhance the construction of biological defense capabilities, and strengthen rapid and effective responses to biological incidents.

On the other hand, in contrast to western countries, which focus on external issues related to national security, such as responding to emergencies, homeland security, and protection of overseas interests, the security concept of China pays more attention to domestic governance. In the country, biosafety/biosecurity focuses more on internal governance, especially in terms of human safety, health, disease prevention, and even microbial resistance. This stance reflects the primary need for biosafety/biosecurity governance as a developing country with a large population and illustrates that China's biosafety/biosecurity concept remains in the process of development. The Biosecurity Law of the People's Republic of China covers a wider range of legislation than do similar laws in other countries.

The logical development from risk perception to governance goals constitutes the basic starting point and destination of the security concept and governance philosophy. The realization of the leap between the two is the core element of the security concept, including the recognition of risks and the type of governance goals to achieve. According to Article 2 of the National Security Law of the People's Republic of China, "national security" means a status in which the regime, sovereignty, unity, territorial integrity, welfare of the people, sustainable economic and social development, and other major interests of the state do not relatively face any danger, are not internally or externally threatened, and possess the capability to maintain a sustained security status.[1] This security concept is a complete one based on the progressive logic chain of *threat-state-capability*. Its starting point is identifying and preventing *threats*, and its goal is to maintain a safe *state*; lastly, its path is to develop the *capability* to maintain this state.

Based on the abovementioned security concept, China's concept of biosafety/biosecurity clearly focuses on threats, seeks a state of non-threat, and

[1] National Security Law of the People's Republic of China (2015), adopted at the 15th session of the Standing Committee of the Twelfth National People's Congress of the People's Republic of China, http://www.npc.gov.cn/zgrdw/npc/lfzt/rlys/2014-08/31/content_1876769.

develops the ability to maintain this state. Article 2 of the Biosecurity Law of the People's Republic of China stipulates that, "biosecurity" means that the state effectively prevents and responds to the threat of dangerous biological agents and related factors. Furthermore, biotechnology can develop steadily and healthily, neither the lives and health of the people nor the ecosystems is relatively in danger or under threat, and it possess the capability in the biological field to maintain national security and sustainable development.[1]

From the perspective of threat cognition and after its evolution in practice, China's cognition of biosafety/biosecurity risks has been greatly enriched, and a system with a wide coverage has been formed, including eight fields, namely, preventing and controlling a major new or sudden outbreak of an infectious disease or an epidemic in animals or plants; researching, developing, and applying biotechnology; biosecurity management of pathogenic microbe laboratories; biosecurity management of human genetic and biological resources; preventing the invasion of alien species and protecting biodiversity; responding to antimicrobial resistance; preventing biological terrorist attacks, and defending against the threat of biological weapons and other biosecurity-related activities.[2]

From the perspective of pursuit, China has formed a quaternary concept of biosecurity, that is, unity among national, human, development, and common security. On February 14, 2020, at the 12th meeting of the Central Committee for Comprehensively Deepening Reform, General Secretary Xi Jinping pointed out that biosafety/biosecurity must be incorporated into the national security system, the construction of a national biosafety/biosecurity risk prevention, control, and governance must be systematically planned, and national capabilities on biosafety/biosecurity governance must be improved. Moreover, these initiatives must be considered from the perspectives of protecting the health of the people, ensuring national security, and maintaining long-term national stability. Toward this end, promoting the promulgation of the Biosecurity Law as soon as possible and accelerating the establishment

[1] Biosecurity Law of the People's Republic of China (2020), http://www.npc.gov.cn/npc/c30834/202010/bb3bee5122854893a69acf4005a66059.shtml.

[2] Ibid.

of a national biosafety/biosecurity legal system and an institutional guarantee system are necessary. Article 1 of the Biosafety/Biosecurity Law of the People's Republic of China clearly states that this law is enacted for the purposes of maintaining national security, guarding the lives and health of the people, promoting the sound development of biotechnology, and boosting the construction of a community with a shared future for mankind. The starting point of China's biosecurity is national security, its foothold is human security, and its goal is to protect human health. Nevertheless, development must be sought while maintaining security; the common security of mankind must be promoted while maintaining its security.

From the perspective of its path of realization, the essential requirement of the biosafety/biosecurity concept of China is to grasp the laws based on major changes in international order, to make overall plans based on the major premise of risk prevention, and plan based on important strategic opportunities for China's development. In the field of biosafety/biosecurity, its essence is to grasp the politicization of biosafety/biosecurity issues due to the reshaping of international order and changes in international geopolitics. On the basis of the premise of risk prevention, China's biosafety/biosecurity concept not only highlights the many new characteristics of national biosecurity risks and prevents major national biosecurity risks but also illustrates the weaknesses of the national risk prevention/control and governance system for biosafety/biosecurity. Against the background of a strategic period of opportunity, China's concept of biosafety/biosecurity aims to maintain, form, and extend the opportunity and window periods of biosafety/biosecurity governance.

B. China's Biosafety/Biosecurity Governance Thoughts

Governance thinking intends to implement the security concept. At present, the core objectives of China's biosafety/biosecurity governance are mainly reflected in analyzing the bioasfety/biosecurity situation in the country, elucidating the risks and challenges, and clarifying the ideas and measures for strengthening the construction of biosafety/biosecurity. The understanding of these governance goals mainly includes three aspects.

The first is that the situation of biosafety/biosecurity in China is as follows: the three major problems of traditional biosecurity (i.e., biological weapons, bioterrorism attacks, and large-scale infectious diseases) are severe. A range

of new biosafety/biosecurity risks has increased. As a country with a large population, a large agricultural economy, and an extremely rich and relatively fragile ecological environment, China continues to face many internal biosafety/biosecurity risks. The alien threats to biological security are also increasing, including imported alien species, pests and plant diseases, infectious diseases, theft of biological resources, and biotechnology espionage.

Second, the risk challenge lies in the fact that old problems and new risks are intertwined, which increases the threat of biosecurity risks. An example is the expansion of the field. From old problems to new risks, the types and categories are continuously expanding, and a number of new risks that previously did not attract attention are also simultaneously brewing. The next is that the expansion of the field leads to the complexity of the relationship among risks, which makes conducting risk assessment and control increasingly difficult. Also China's degree of openness continues to increase, and exogenous and imported threats, such as large-scale transnational epidemics, alien species invasion, biological weapons proliferation, and bioterrorism, are embedded in the process of globalization. This notion exacerbates the uncertainty and complexity associated with biological risks. Therefore, the object of governance has exceeded the previous single risk and expanded to multiple, compound, and comprehensive risks. Among them, the prevention and control of major and systemic risks in biosecurity is becoming the top priority.

Third, the core of the ideas and measures for strengthening the construction of biosafety/biosecurity is to continuously improve the biosecurity governance system and capabilities. Four improvements are necessary. The first pertains to the national biosecurity governance system followed by the biosecurity governance mechanism; the third denotes the national biosecurity legal system and institutional guarantee system; the fourth refers to the support and guarantee capabilities of biosafety/biosecurity governance, including support for decision-making, technology, information, and talent support, among others.

III. China's Biosafety/Biosecurity Governance System

The governance system stands for the specific implementation of governance ideas under the guidance of the security concept. After continuous

improvement in recent years, China has formed a relatively comprehensive biosafety/biosecurity governance system. In general, the biosafety/biosecurity governance system covers a complete set of solutions, including governance concepts, national strategies, legal systems, institutional guarantees, and management systems.

China's statement on the construction of its biosafety/biosecurity governance system is that improving it, strengthen strategic and forward-looking research and planning, and reinforcing its national biosecurity strategy are necessary initiatives. Moreover, further developing the biosafety/biosecurity governance mechanism in terms of party committee leadership, government responsibility, social coordination, public participation, and legal protection and strengthening the coordination mechanism for work related to biosafety/biosecurity at all levels are crucial steps. Thus, efforts must be made in various aspects, such as legislation, law enforcement, judiciary, law popularization, and abidance with the law. In this manner, national biosecurity laws, regulations system, and institutional guarantee system can be enriched; biosecurity laws, regulations, and knowledge publicity and education can be strengthened, and the awareness of the entire society about risk prevention in biosafety/biosecurity can be increased. In addition, consolidating the foundation of joint and mass prevention and control and giving full play to the role of the people in this regard is vital. The structure of China's biosafety/biosecurity governance system can be further refined as follows. Under the guidance of the biosafety/biosecurity concept and according to the national biosecurity strategy, a trinity governance structure composed of legislation, law enforcement, and administration is formed. Among them, the top-level design of the legislation is the Biosafety/Biosecurity Law of the People's Republic of China, based on which laws in various fields are gradually revised, abolished, and perfected. In terms of law enforcement, 11 biosafety/biosecurity systems are mainly established, and biosafety/biosecurity governance is standardized within an institutional framework. For administration, a governance structure that performs its duties is formed through reliance on the design of the institutions and functions of the government. Such a governance system is still in the process of continuous improvement.

A. National Strategy

China's biosecurity strategy can be summarized as follows:

Implement the overall national security concept, implement the biosafety/biosecurity law, coordinate development and security, strengthen the national biosecurity risk prevention and control and governance system in accordance with the principles of people-oriented, risk prevention, classified management, and coordination, improve the national biosecurity governance capacity, and effectively build a national biosecurity barrier.

China's biosecurity strategy has several characteristics. First, it is holistic, integrated, and synergistic. Biosecurity should be viewed from the perspective of linkage with other national security issues, and system thinking should be applied to the view as a whole. Furthermore, security should be ensured without hindering development and should be sought in development instead of doing so in a one-sided manner. Synergy among various fields, sectors, and society as a whole should be enhanced. Second, the strategy promotes the improvement of capabilities for biosecurity governance in accordance with the law; highlights system construction; improves the effectiveness of governance, administration, and decision-making; and realizes the modernization of the governance system and capabilities in the field of biosafety/biosecurity. Third, emphasis on risk prevention and control should not be confined to crisis management and crisis prevention but should be based on risk prevention, strengthening the prevention and control of biosafety/biosecurity risks, and a strong security barrier. Under the guidance of this strategy, China has promoted legislation related to biosafety/biosecurity, strengthened the reform and coordination of the biosafety/biosecurity governance system, and increased investment in risk prevention.

B. Guarantee of the Rule of Law

In 2021, China promulgated the Biosecurity Law of the People's Republic of China, whose objective is to strengthen the rule of law in biosecurity and promote law-based governance and administration in the field of biosecurity. At the same time, regulations in various fields related to biosafety/biosecurity were also developed and improved. China gradually formed a system of laws and regulations for biosafety/biosecurity on the basis of the Biosecurity Law of the People's Republic of China, which covers various fields, levels, and regions of biosafety/biosecurity.

The focus of this system is on the following aspects.

First, it intends to maintain national security. Bioterrorist attacks, misuse and abuse of biotechnology, laboratory biosecurity, and other nontraditional biological threats have come to the fore. Thus, an urgent need emerges to adopt biosecurity legislation to address these challenges. The law should be used to delineate the boundary of biotechnology development, guide and regulate the research and application of biotechnology, promote the healthy development of biotechnology, and prevent and reduce harm due to biotechnology infringement.

Second, it aims to build a national biosecurity system. Toward this end, an effective management system and mechanism through legislation should be established, corresponding legal systems and measures should be improved, the biosafety/biosecurity code of conduct for all aspects of society should be clarified, the obligations of public administrations, social organizations, and individual citizens should be defined, and the material basis and conditions for responding to biological threats should be protected and applies.

Third, it endeavors to enhance national biosecurity capabilities. Currently, China has the potential in biotechnology research and development and infrastructure construction. Nevertheless, a gap remains compared with developed countries in terms of technology, products, and standards. Therefore, incorporating capacity building for national biosecurity into the law can encourage the independent innovation of industrial, scientific, and technological policies with a focus on mastering core key biotechnology, guaranteeing and promoting the development of China's biotechnology in accordance with the law, and improving the ability to prevent risks and threats.

Fourth, it aspires to participate in and strengthen international governance. In response to biological threats and challenges, the international community has accelerated the process of building the rule of law. For example, the United Nations has adopted international conventions such as the Convention on the Prohibition of Biological Weapons, Convention on Biological Diversity, International Convention for the Protection of New Varieties of Plants, and International Plant Protection Convention. China has ratified these conventions and made solemn commitments. The enactment of a biosecurity law is conducive to the prevention of biological threats and cooperation with other countries worldwide to maintain international security and stability.

C. Institutional Guarantee

Articles 14 to 24 of the Biosecurity Law of the People's Republic of China establish 11 systems, which mainly cover the following aspects.

The first refers to evaluation and early warning, such as monitoring and early warning, investigation and evaluation, and review systems for biosecurity risk. The coordination mechanism for work related national biosecurity organizes the establishment of a national risk monitoring and early warning system to improve risk identification and analysis capabilities. According to data and other information on risk monitoring, regular investigation and assessment of biosecurity should be organized. Relevant departments of the State Council can conduct reviews of major biological issues that influence or may influence national security to effectively prevent and resolve these risks.

The second discusses certification and licensing, that is, the national access system for high-risk biological factors and the response system for major overseas biosafety incidents. Customs will address biosecurity risks found in entry, exit, and transit in accordance with the law. Personnel, means of transport, goods, and articles, among others, that will be evaluated as high-risk biosecurity should enter the country through designated border ports, and stringent risk prevention and control measures should be taken. In the event of major biosecurity incidents abroad, customs will take emergency measures for prevention and control in accordance with the law, strengthen certificate verification, increase inspection ratio, and suspend the entry of relevant personnel, means of transportation, goods, and articles, among others. If necessary, it may temporarily close relevant ports, conduct a blockade of relevant borders, and take other measures with the approval of the State Council.

The third describes information release and sharing, which pertains to sharing and release systems for information on biosecurity. The national coordination mechanism for biosecurity organizes the establishment of a unified national information platform, and the relevant departments should submit biosecurity data, materials, and other information to the national information platform to achieve information sharing. The overall national situation in terms of biosecurity, major risk warning information, major incidents and corresponding investigation and handling information, and

other major biosecurity information should be released by member units of the national biosecurity coordination mechanism according to the division of responsibilities. Other information on biosecurity should be released by the relevant departments of the State Council and local governments at or above the county level and their relevant departments according to their duties and authorities. At the same time, the law also stipulates that no unit or individual shall fabricate or disseminate false information on biosecurity to prevent possible unstable factors in this field.

The fourth highlights inventory and standardization, which includes catalog/list and biosafety/biosecurity standard systems. The State Council and its relevant departments will, according to the needs of biosecurity work, formulate and publish catalogs or lists of materials, equipment, technologies, activities, important biological resource data, infectious diseases, animal and plant diseases, and invasive alien species related to biosecurity and dynamically adjust them. The standardization department of the State Council and other relevant departments will formulate and improve relevant standards in the field of biosecurity according to their division of responsibilities. The national coordination mechanism for biosecurity will organize the relevant departments to strengthen the coordination and connection of biosafety standards in different fields and to establish and improve the biosafety standard system.

The last one addresses crisis handling and pre-drills, including the investigation of biosafety/biosecurity incidents and traceability and emergency response systems. In the occurrence of major emerging infectious diseases, animal and plant epidemics, and biosafety incidents of unknown causes, the national biosecurity coordination mechanism should organize investigations and trace the source, determine the nature of an incident, comprehensively assess the impact of the incident, and provide opinions and suggestions. The relevant departments of the State Council will organize and formulate emergency plans for related incidents in relevant fields and industries and conduct emergency drills, emergency responses, emergency rescues, and post-event recovery in accordance with the emergency plans and unified deployment.

These 5 aspects and 11 mechanisms ensure a relatively complete composition of the implementation measures for biosafety/biosecurity governance in China, which have three characteristics. The first is the unification of leadership and

the strengthening of the order of the system; the second denotes the broad participation of the public, which gives full play to the subjectivity of the people, highlights the role of the community at the grassroots level, and forms a joint force composed of the entire society; the last is its reliance on the rule of law and strengthened coordination.

D. Management System

China's biosafety/biosecurity governance implements a departmental management system under the coordination mechanism to coordinate behavioral processes. On the basis of giving full play to departmental management, the coordination mechanism will manage and resolve disputes and issues that require organization. This system is mainly composed of five measures.

The first is to establish a national coordination mechanism for biosecurity. Provinces, autonomous regions, and municipalities, which are directly under the Central Government, should establish work coordination mechanisms for biosecurity to organize, coordinate, and supervise the advancement of related work within their administrative regions. The second emphasizes the national coordination mechanism for biosecurity, which analyzes and determines the national situation and organizes, coordinates, and supervises the advancement of national biosecurity-related work. Third, the national coordination mechanism establishes an expert advisory committee to provide decision-making advice for the research strategies on national biosecurity, policy formulation, and implementation. Fourth, local governments at all levels are responsible for biosecurity work within their respective administrative regions. Thus, relevant units and individuals should cooperate in the prevention and control of biosecurity risks and emergency responses. The fifth covers institutional adjustment. For example, the National Health Commission of the People's Republic of China (i.e., the National Bureau of Disease Control and Prevention and the Department of Medical Emergency Response) was adjusted, and the National Committee of Science and Technology Ethics was established.

IV.Chinese Characteristics and Global Significance

The biological threat is a new challenge faced by mankind, and biosafety/biosecurity governance is a common problem for mankind. The fundamental reason is that the characteristics of biotechnology have resulted in differences in the thinking, logic, and practice of biosafety and other security issues in terms of research paradigms and coping methods, which are prominently reflected in three aspects.

The first is the complex interrelationship of multiple factors in biosecurity crises. Biological security pertains to security for human beings. Whether or not it is public health, food, medicine and vaccine, agriculture, forestry, animal husbandry and fishery, species ecology, or new biotechnology, the new threats, ethics, and challenges are related to human security. Biosecurity issues interact with other security issues in a complex manner through deep links with human security. The challenges to biosafety/biosecurity governance frequently exceed the realm of biotechnology and involve a wide range of complex factors such as national security, social stability, culture, and ethnic identity. As such, it must be governed in a highly forward-looking and comprehensive manner. The second stands for the integration of domestic and international governance. Biosecurity is a typical global issue, which faces the problem of interconnection between national and international security. In the face of cross-border challenges to biosecurity, strengthening international cooperation and participating in international governance are necessary measures in parallel with national governance. The third denotes the synergy between the government and nongovernment. The difficulty of governance lies in the cooperation between government and nongovernment, as enterprises, institutions, and even individuals use biotechnology. Importantly, in the occurrence of biosecurity crises, governments need to rely on communities, nongovernment organizations, and voluntary organizations. To solve the abovementioned problems, China has formed a unique concept of biosecurity and its governance system through continuous exploration and practice.

A. Inclusiveness and Integration

China's biosafety/biosecurity concept and governance are highly inclusive, which cover a wide range of biosecurity threats and are continuing to expand. In

contrast to the western concept of biosafety/biosecurity, China incorporates all contents related to biological threats in one basket. Hazardous biological agents and related factors and threats, as defined in the Biosecurity Law of People's Republic of China, as well as seven specific activities that threaten national biosecurity partially fall within the scope of international public health security. Therefore, China's biosecurity issues include technical and environmental governance as well as arms control issues. This definition is mainly based on the fact that although biosecurity involves many fields, commonalities exist in governance measures; thus, China's biosecurity problems can be managed in an integrated manner.

This comprehensive governance idea emphasizes certain significance in the history of the development of international biosecurity. First, biosecurity is viewed from the perspective of linkage with other national security issues, and systemic thinking is used to elucidate the entire picture instead of merely viewing specific areas, technology categories, and industries to identify problems and formulate corresponding policies. Second, this concept of biological security highlights coordinated development and security. This aspect is crucial to the dual relationship between biosecurity and bioindustry: to ensure security without impeding development, to seek security in the course of development, and not to seek security in a one-sided manner. For this reason, when China promulgated the Biosecurity Law of the People's Republic of China, it also launched the plan to spur the bioeconomy during the 14th Five-Year Plan period (2021–2025).[1] Finally, enhancing the effectiveness of the synergy among various fields, sectors, and society as a whole and implementing it as a principle are important steps. During major and sudden public health crises, China has demonstrated that it mobilizes all aspects of society with an integrated, systematic, and coordinated mindset to focus on prevention and control and eliminate the impact as soon as possible. This expression is a concentrated one of China's advanced thinking and strengths in biosafety/biosecurity governance.

[1] China Unveils Five-year Plan for Bioeconomy, the National Development and Reform Commission, https://en.ndrc.gov.cn/netcoo/achievements/202205/t20220520_1326683.html.

B. Preventive Governance

The difference between Chinese and western concepts and strategies of governance mainly lies in the difference between preventive governance and crisis management. The fundamental idea of biosecurity governance in the United States is the use of the law of crisis management to address biosecurity threats and crises. Based on this notion, the National Biodefense Strategy of the United States decomposes the thinking of addressing biosecurity into five stages, namely, actively and effectively prevents, prepares for, responds to, recovers from, and mitigates risk from natural, accidental, or deliberate biological threats.[1] This concept is the cyclical evolution of the four stages of crisis management, namely, ordinary time, pre-crisis, crisis, and post-crisis.

China's biosecurity governance is more preventive. It is mainly reflected in that prior to the occurrence of a crisis, strengthening risk prediction, pre-arranging resources in advance, and preventing and resolving risks are necessary initiatives. At the same time, it emphasizes risk prevention and control and strengthens the prevention and control of biosecurity risks on the basis of risk prevention to establish a security barrier. This idea is expressed in China's long-term plan for 2035, which is a medium- and long-term governance concept with Chinese characteristics. This form of preventive governance is a concept passed on continuously by Chinese Communists and successive Chinese governments. It is also one of the outstanding features of China's political system. This characteristic is contained in the stage of the birth of the political system. Looking back at history, Mao Zedong proposed that "one cannot be called a leader without foresight, but for leadership one must foresee" during the process of establishing the new Chinese government. In today's Chinese governance, preventing and resolving risks form the core concepts of national governance, which are simultaneously advancing with top-level governance ideas such as "coordinating development and security."

C. Diversified Governance

Since the 18th National Congress of the Communist Party of China, the

[1] *The National Biodefense Strategy*, the White House, 2018, https://trumpwhitehouse.archives.gov/wp-content/uploads/2018/09/National-Biodefense-Strategy.pdf.

Party and the country have attached great importance to the enrichment of concepts and methods related to biosecurity governance and accelerated the transition from society management to governance. Multi-party governance forces unite to form a new pattern of biosecurity governance in which multiple subjects jointly establish, govern, and share.

Diversification of governance philosophy. Biosafety governance does not only pursue a singular goal of *safety and stability.* On the one hand, China's biosafety governance is gradually shifting from a single rigid model, which emphasizes the government's responses to biosafety incidents, to a model that places increased emphasis on the subjectivity of the people in biosafety governance and gradually establishes a grassroots governance foundation and a shared governance system that focuses on the lives and health of the people and that is close to the people. On the other hand, the biosafety governance policy exhibits the dual nature of safety supervision and technology promotion. It not only restricts behaviors that may endanger safety from the standpoint of governance norms but also promotes behaviors that are beneficial to the development of biotechnology and the health and well-being of the people. While preventing and responding to risks, it builds a strategic scientific and technological force for realizing the coordinated advancement of development and security.

Governance subjects are diversified. During the SARS period, the government was the sole subject of biological risk response. With the development of practice, the cooperation among the government, science and technology systems, and social organizations has generated an institutionalized basis for the formation of a governance pattern with one core and multiple elements. With unified leadership as the core and government power as the leading force, China has fully mobilized the enthusiasm and initiative of various social forces to encourage science and technology systems, social groups, media, industries, and individual citizens to become multiple subjects of biological risk governance. Moreover, they were urged to participate in the national biosafety governance system and capacity building in an orderly manner to achieve a common responsibility for security, common participation in the construction of the governance system, common prevention of biological risks, and the common sharing of achievements and results in bioscience, technology, and

security.

Diversification of governance tools and vehicles. The tools for biosafety governance have gradually changed from direct intervention by a single administrative directive to administrative supervision on a legal basis. At the same time, new governance tools, such as social coordination, public participation, and scientific and technological support, are gradually being applied to the process of biosecurity risk governance. This toolbox is becoming increasingly rich and diverse. In addition, technological systems and grassroots communities, as informal governance actors, have also begun to play important roles in responses to public health crises.

D.International Collaboration and Security Initiative

The issue of biosecurity is the most prominent and common proposition of all mankind and the most representative issue of a community with a shared future for mankind. Thus, active participation in global biosecurity governance is required, coordination with the international community is necessary to address increasingly severe biosecurity challenges, and strengthened bilateral and multilateral cooperation and exchanges are important for policy formulation, risk assessment, emergency response, information sharing, and capacity building in terms of biosecurity. This idea of international cooperation is mainly reflected in the concept of a community with a shared future for mankind. This idea is not only an overall world view for understanding the development of a new round of scientific and technological revolution represented by biotechnology but also a practical methodology. The interaction between the two is worthy of in-depth exploration and active action.

In terms of concrete actions, China regards think tank diplomacy as the Track Two Diplomacy for its international exchanges and cooperation to implement the Global Security Initiative and respond to global issues such as biosecurity. Furthermore, it leads the international biotech industry by creatively initiating crucial international public goods. The most representative achievement is the first international biosafety initiative named after a Chinese city and mainly based on Chinese initiatives, that is, the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists (hereafter, the Tianjin Guidelines). The Tianjin Guidelines is a product of the process of advocating responsible scientific research dialogue under the framework of

the Convention on the Prohibition of Biological Weapons. China and Pakistan first initiated the Tianjin Guidelines in 2016, and Tianjin University joined forces with Johns Hopkins University to actively promote it in the international scientific community. The Tianjin Guidelines contain 10 guiding principles and standards of conduct and advocate the improvement of biosafety awareness among researchers in terms of responsible conduct of research, dissemination of research findings, public engagement, and international cooperation. The Tianjin Guidelines have now been approved by the InterAcademy Partnership and promoted to more than 150 national academies worldwide. Moreover, Global Guidance Framework for the Responsible Use of the Life Sciences: Mitigating Biorisks and Governing Dual-use Research of the World Health Organization has recognized it as a high-level principle. Thus, it has become an important initiative in the area of biosecurity in The Global Security Initiative Concept Paper of the Chinese government.

In addition to the abovementioned concepts of governance, the biosafety/biosecurity concept and governance system of China are still being developed and improved in practice under the guidance of the overall national security concept. This perfection is not based on creative design or academic theory but is derived from practice. This notion is also in line with the basic law of the development of the biosafety/biosecurity governance system. Therefore, the process must be viewed from crisis to practice and experience accumulation, and it must be understood that China, similar to western countries, is in the process of continuously improving its governance system. Another aspect that must be recognized is that China has provided a pioneering concept for governance and governance system with its practice and presented the international community with a set of Chinese solutions for biosafety/biosecurity governance. Its characteristics are mainly reflected in comprehensive coordination, preventive governance, diversity governance, and international collaboration. A better understanding of this set of concepts (biosafety/biosecurity thinking), including governance concepts and systems with Chinese characteristics, will provide added wisdom and further options for international governance on biosafety/biosecurity.