China’s evolving biosafety/biosecurity legislations

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ABSTRACT

This paper represents a systematic effort to describe and assess China’s evolving biosafety/biosecurity legislative and regulatory regime. It catalogs and analyzes laws, regulations, and measures, including the newly passed Biosafety/Biosecurity Law. Various reasons are underlying China’s recently accelerating legislative process for such a law, from international attention increasingly turning biosafety/biosecurity governance into a more regular fixture; the emergence of infectious diseases and even pandemics linked with zoonosis; advances in the global frontier of the life sciences and biotechnology and their integration with other technologies, which, while holding great promise for advancements in global health, raises biosafety/biosecurity concerns; to the strengthening of biosafety/biosecurity governance in many countries. Chinese leadership’s ‘holistic view of national security’ encompasses broad areas of concerns of national security with biosafety/biosecurity being an integral part. However, having progressed alongside its development of the life sciences and biotechnology, China’s current biosafety/biosecurity legislative and regulatory regime is far from rising to the challenges and even the newly enacted Biosafety/Biosecurity law still has room for improvement. The paper’s findings have significant policy implications for further enhancing China’s biosafety/biosecurity legislation and governance and making them better serve domestic interests while converging with international norms.

KEYWORDS: biosafety, biosecurity, legislation, governance, China

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I. INTRODUCTION

China is accelerating the construction of its biosafety/biosecurity legislative regime. Since China started to develop biotechnology in the 1980s, there have been calls for a law of biosafety, whose urgency is on the rise especially given the new attention to biosafety/biosecurity in the wake of the outbreak of a novel coronavirus disease, COVID-19, which has been ravaging globally since late 2019 and touching upon many of the issues implicated by such a statute. China’s National People’s Congress (NPC), the legislature, has finally moved forward on the legislation (Table 1). In 2018, the first session of the 13th NPC included making the law into one of the Class-Three legislative projects, or those legislations that are premature and need further research and deliberation. In 2019, the NPC Environmental Protection and Resources Conservation Committee was tasked with leading the drafting of the law. The Standing Committee of the 13th NPC reviewed and debated the first two drafts of the law at the 14th and 17th meetings, in October 2019 and April 2020, respectively; and the second draft also was reviewed and debated at the third session of the 13th NPC in May. Then, there was a period for public comment on the draft law in the months of May and June. The third draft of the law had a review during the 22nd meeting of the 13th NPC Standing Committee before being passed on October 17. The law took effect on April 15, 2021, thus finalizing the institutionalization of China’s biosafety/biosecurity legislations and marking a major milestone for China’s biosafety/biosecurity governance.

The Chinese term, ‘shengwu anquan,’ used in the name of the law, denotes the protection of humans, animals, plants, and the environment from hazards or potential risks under two circumstances. The first, biosafety, is about such protection from the risks and hazards caused inadvertently by working with microorganisms and toxins and the second, biosecurity, refers to such protection from the hazards that may arise in connection with deliberate theft, misuse, or diversion of biotechnology. Therefore, ‘shengwu anquan’ in a narrow sense is about biosafety but broadly biosecurity; as such, biosafety and biosecurity are distinct but closely related. In particular, intended to prevent accidents, biosafety measures designed to reduce accidental biological risks can indirectly help to mitigate intentional biosecurity hazards associated with challenges that ‘the same scientific research, products, or facilities which are meant for social good could also have an unintended result of threatening a population.’ Not paying...
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Table 1. Legislative timeline of China’s biosafety/biosecurity law

| Date         | Event Description                                                                                     |
|--------------|-------------------------------------------------------------------------------------------------------|
| March 2018   | The first session of the 13th National People’s Congress (NPC) designated the biosafety/biosecurity law |
| February 2019| The Legislative Affairs Committee of the 13th NPC convenes an expert forum on the legislation on the law |
| July 10, 2019| Li Zhanshu, a member of the Standing Committee of the Politburo of the Chinese Communist Party’s Central Committee and chairman of the NPC Standing Committee, presides over a forum to solicit opinions and suggestions on the law |
| September 2019| The 13th NPC Standing Committee includes the promulgation of the Biosafety/Biosecurity Law into its annual legislative plan for the first time with the NPC Environmental Protection and Resources Conservation Committee leading the drafting |
| October 21, 2019| The first draft of the law is submitted to the 14th meeting of the 13th NPC Standing Committee for review |
| April 2020   | The second draft of the law goes through a review at the 17th meeting of the 13th NPC Standing Committee |
| May 2020     | The draft law is reviewed and deliberated in the third session of the 13th NPC |
| May 3 to June 13, 2020| Public views on the draft law are solicited via the NPC website |
| June 1, 2020 | The legislation of the law is included in NPC’s legislative work plan for 2020 |
| September 2, 2020| The NPC Constitution and Law Committee convenes to review the draft law |
| September 27, 2020| The NPC Legislative Affairs Commission convenes to solicit views from relevant parties on feasibility of main institutional norms in the draft law, as well as timing, social effects, and possible problems associated with the implementation of the law |
| September 29, 2020| The NPC Constitution and Law Committee convenes to review the draft of the law |
| October 17, 2020| The 22nd meeting of the 13th NPC Standing Committee passes the law after reviewing its third draft |
| April 15, 2021| The law comes into force |

Source: National People’s Congress (NPC), The Biosafety/Biosecurity Legislation (in Chinese), http://www.npc.gov.cn/npc/swapkf/swaqlf.shtml (accessed May 5, 2021).

Attention to biosafety/biosecurity would pose potentially catastrophic consequences to a country’s political, social, and economic development, public health, and ecology and the environment. China’s biosafety/biosecurity legislations need to be understood in such contexts.

This paper represents a systematic effort to describe and assess the evolution of China’s biosafety/biosecurity legislative regime. The next session outlines the background against which China has endeavored to beef up its biosafety/biosecurity leg-
China’s evolving biosafety/biosecurity legislations. This is followed by an analysis of China’s biosafety/biosecurity legislative and regulatory regime up to the passage of the Biosafety/Biosecurity Law in 2020 so as to lay a foundation for examining the most recent development as well as the deficiencies that exist in China’s biosafety/biosecurity legislations. China’s biosafety regime for agricultural genetically modified organisms (GMOs) is used to illustrate its legislative practice. The paper then takes a preliminary reading of China’s biosafety/biosecurity law passed by the NPC. It will conclude with a prospect of China’s biosafety/biosecurity legislations and governance.

II. RESPONSES TO INTERNATIONAL AND DOMESTIC DEVELOPMENTS

Developments at several fronts have prompted China to accelerate biosafety/biosecurity legislations. First, international attention has increasingly turned biosafety/biosecurity governance into a more regular fixture, as evidenced by the introduction of relevant international treaties. In 1988, the United Nations Environment Programme (UNEP) explored the need for a Convention on Biological Diversity (CBD), which became effective in late 1993, with biosafety as one of the important components. Afterward, the international negotiation on CBD’s implementation, conducted under the UNEP, focused, among other issues, on potential threats of GMOs to biodiversity, the environment, and human health (1992). The Cartagena Protocol on Biosafety to implement the CBD was adopted in 2000 as a risk assessment and regulatory framework governing the cross-border movements of GMOs (2000). Meanwhile, in June 1992, the United Nations (UN) adopted Agenda 21 as a comprehensive plan of action to build a global partnership for sustainable development to improve human lives and protect the environment. The UN declared Millennium Development Goals (MDGs) in 2000 to encourage a global combined commitment for addressing challenges facing the 21st century and MDGs evolved into Sustainable Development Goals in 2012.

These developments need to be examined against a globally challenging background. For example, according to a UNEP report (2017), approximately 700,000 people worldwide die each year from drug-resistant bacterial infections; in a global biodiversity assessment, the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services, under the United Nations Educational, Scientific and Cultural Organization, warned that one in eight species are in danger of extinction. Although the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons on their Destruction, also known as the Biological Weapons Convention (BWC), was open for signature in

4 United Nations, Convention on Biological Diversity (Nairobi: United Nations, 1992).
5 United Nations, Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Montreal: Secretariat of the Convention on Biological Diversity, 2000).
6 Longyu Shi, Linwei Han, Fengmei Yang, and Lijie Gao, The Evolution of Sustainable Development Theory: Types, Goals, and Research Prospects, 11 Sustainability 7158 (2019).
7 United Nations Environment Programme (UNEP), Frontiers 2017 Emerging Issues of Environmental Concern (Nairobi: UNEP, 2017).
8 Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES), Global Assessment Report on Biodiversity and Ecosystem Services (Bonn, Germany: IPBES Secretariat, 2019).
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1972 and came into force in 1975, the rising threats of bioterrorism have made global governance necessary.9 Second, past two decades have witnessed the emergence of infectious diseases and even pandemics linked with zoonosis, from severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), H1N1 influenza, to now COVID-19. In retrospect, in 1951, the World Health Organization (WHO) introduced the International Health Regulations (IHRs), a binding international legal instrument addressing public health risks of international concern, which have been revised several times to respond to the changes of the most dangerous infectious diseases. Among others, the IHRs require that each member state report any disease outbreaks and certain public health events to the WHO.10 Given that infectious diseases present risks that cannot be tackled by any one country, there has been increasing urgency about not only globally coordinated and efficient disease detection, assessment, reporting, and response systems in animal and human health but also globally explicit recognition of the existence of a health–security nexus.11 Established in 2014, Global Health Security Agenda is now a network of 69 countries, which works together with international and nongovernment organizations and private companies to secure global health security.12

Third, advances have been made at the global frontier of the life sciences and biotechnology, especially in bioinformatics, genomics, gene editing, systems biology, and synthetic biology. And the life sciences and biotechnology also have become increasingly integrated with nanotechnology, information technology, artificial intelligence, precision electronics, optoelectronic engineering, micromanufacturing, and delivery technologies.13 As well as holding great promise for advancements in global health, the progress would have significant implications for biosafety/biosecurity governance.14 For one thing, laboratory-acquired infection (LAI), or mismanagement in which microorganisms escape from laboratories, highlights the necessity to raise

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9 W. Seth Carus, The History of Biological Weapons Use: What We Know and What We Don’t, 13 HEALTH SECUR. 219–255 (2015).
10 Kathryn E. Bouskill and Elta Smith, Global Health and Security: Threats and Opportunities (Santa Monica, CA: RAND Corporation, 2019).
11 Julie E. Fischer, Sarah Kornblet and Rebecca Katz, The International Health Regulations (2005): Surveillance and Response in an Era of Globalization (Washington, DC: Stimson Center, 2011); Bouskill and Smith, supra note 10; Zhou et al., supra note 2.
12 Suman M. Paranjape and David R. Franz, Implementing the Global Health Security Agenda: Lessons from Global Health and Security Programs, 13 HEALTH SECUR. 9–19 (2015); Bouskill et al. supra note 10; Sabrina Brizee, Katherine Budeski, Wilmot James, Michelle Nalbandian, Diediker A. Bleijs, Scott J. Becker, Sacha Wallace-Sankarsingh, Anthony Ahumibe, Emmanuel Agogo, Chikwe Ihekweazu, Simo Nikkari, Maureen Ellis, Ernesto Gozzier, Immaculate Sware Semesi, Zibusiso M. Masuku, Aamer Ikram, Faheem Tahir, Irma Makalinao, Hayley Anne Severance, Mark W. J. van Passel, and Elizabeth E. Cameron, Accelerating Action in Global Health Security: Global Biosecurity Dialogue as a Model for Advancing the Global Health Security Agenda, 17 HEALTH SECUR. 495–503 (2019).
13 Deutscher Ethikrat, supra note 3 in chapter 2; Kolja Brockmann, Sibylle Bauer, and Vincent Boulanin, The Convergence of Advances in Biology and Emerging Technologies, in Bio Plus X: Arms Control and the Convergence of Biology and Emerging Technologies Report, Stockholm International Peace Research Institute ed. (Stockholm: Stockholm International Peace Research Institute, 2019), 4–25; Zhou et al., supra note 2.
14 Kolja Brockmann, Sibylle Bauer, and Vincent Boulanin, Governing the Risks of the Convergence of Biology and Emerging Technologies, in Bio Plus X: Arms Control and the Convergence of Biology and Emerging Technologies Report, Stockholm International Peace Research Institute ed. (Stockholm: Stockholm International Peace Research Institute, 2019), 26–38.
the awareness of biosafety. A particular line of research, ‘gain of function,’ is aimed at improving understanding of disease-causing pathogens and viruses, their interaction with human hosts, and/or their potential to cause pandemics by enhancing the pathogenicity or transmissibility of such agents, which has generated rampant worries about potential risks associated with the misuse and abuse of the information or products resulting from such research.¹⁵

Fourth, many countries have strengthened their biosafety/biosecurity governance. Since 2010, the USA has issued a series of biosafety/biosecurity-related policies. In general, oversight of biological science activities in the USA is governed through three channels—legal statutes and regulations; guidelines and guidance set up by funding agencies; and voluntary policy implementation of unregulated science or entities.¹⁶ In addition to high-level strategies—the Bioeconomy Blueprint (2012) and National Biodefense Strategy (2018)—under the Obama and Trump administrations, respectively,¹⁷ there have been specific policies, from Next Steps: Biosafety and Biosecurity (2014), Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (2014), National Strategy for Modernizing the Regulatory System for Biotechnology Products (2016), to Recommended Policy Guidance for Departmental Development Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO) (2017).¹⁸ A National Science Advisory Board for Biosecurity was established to advise the American government on the evaluation and oversight of proposed dual-use and gain-of-function research.¹⁹

Similarly, in the UK, in 2018, the Department for Environment, Food and Rural Affairs, the Department of Health and Social Care, and the Home Office issued the country’s first Biological Security Strategy to assess three broad categories of future biological threats—natural biological risks, accidental biological risks, and deliberate threats. The European Union also has had a series of multilateral agreements and legislations against the proliferation of biological weapons, as well as those on public health and environmental protection, safety and security measures in laboratories, dual-use technology and measures of secure transport of biohazard materials, and genetic engineering.²⁰

¹⁵ Ruth L. Berkelman, and James W. Le Duc, *Culture of Responsibility*, 345 *Science* 1101 (2014); Nicholas Greig Evans, Marc Lipsitch and Meira Levinson, *The Ethics of Biosafety Considerations in Gain-of-Function Research Resulting in the Creation of Potential Pandemic Pathogens*, 41 *J. Med. Ethics* 901–908 (2015). Michael J. Selgelid, *Gain-of-Function Research: Ethical Analysis*, 22 *SCL. ENG. ETHICS* 923–964 (2016); Peng Gao, Shiwenn Ma, Daru La, Carl Mitcham, Yijia Jing, Guoyu Wang, *Prudently Conduct the Engineering and Synthesis of the SARS-CoV-2 Virus*, 5 *SYNTH. SYST. BIOTECHNOL.* 59–61 (2020).

¹⁶ Kavita M. Berger, Diane DiEuliis, Corey Meyer, and Venkat Rao, *Roadmap for Biosecurity and Biodefense Policy in the United States* (Takoma Park, MD: Gryphon Scientific and Centreville, VA: Parsons, 2018).

¹⁷ Gregory D. Koblenz, *From Biodefence to Biosecurity: The Obama Administration’s Strategy for Countering Biological Threats*, 88 *Int. Aff.* 131–148 (2012); Berger et al., supra note 16.

¹⁸ Jo L. Husbands, *The Challenge of Framing for Efforts to Mitigate the Risks of ‘Dual Use’ Research in the Life Sciences*, 102 *FUTURES* 104–113 (2018).

¹⁹ National Science Advisory Board for Biosecurity (NSABB), *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (Washington, DC: NSABB, 2007).

²⁰ Anna Bielecka and Ali Akbar Mohammadi, *State-of-the-Art in Biosafety and Biosecurity in European Countries*, 62 *ARCHIVUM IMMUNOLOGIAE ET THERAPIÆ EXPERIMENTALIS* 169–178 (2014).
These international developments have given China reasons to take swift and necessary actions. As a frontrunner in certain areas of the global life sciences and biotechnology research and development (R&D), China at the turn of the 21st century contributed to the International Human Genome Project alongside the USA, Germany, the UK, France, and Japan. China has been among the leading countries in the research and commercialization of GMOs. However, China also is facing the challenges of balancing developing the life sciences and biotechnology and adhering to global research norms and bioethics. In the past few years, by taking advantage of gene-editing technologies, for example, Chinese scientists made the first-ever genetic modifications to human embryos in laboratory, which precipitated controversies. Reckless activities such as producing the first known gene-edited babies by editing the genomes of two embryos that were then implanted via in vitro fertilization into the mother’s womb have been condemned by the scientific communities in China and beyond. There has been increasing demand for greater biosafety/biosecurity oversight.

Despite its efforts to build up a biosafety regulatory regime to govern the research and commercialization of GMOs, while being criticized for not engaging an active and systematic participation of scholars from the humanities and social sciences and the public in general, China’s introduction of a comprehensive law of biosafety has been long overdue. In 2004, the mishandling of the SARS virus at the Chinese Centers for Disease Control and Prevention (CDC) resulted in two separate virus-escape incidents infecting eight persons. Seven years later, in the Northeast Agricultural University, a damaging lab outbreak sickened 27 students who contracted brucellosis while dissecting goats in an anatomy course. Such LAIs were more than wake-up calls, not only exposing the limitations of China’s existing biosafety regulatory regime but also posing great challenges to China’s biosafety governance. For healthy development of biotechnology and maintenance of public confidence, China needs to improve its legislative and regulatory regime and address the lack of a law of biosafety that reconciles and coordinates relevant regulations and measures on laboratory biosafety, biotechnology management, biosafety related to GMOs, and others that China has put in place. In particular, there is the need to clarify responsibilities for those involved in the life sciences and biotechnology R&D on top of meeting similar biosafety/biosecurity challenges confronting many countries in the world.

Meanwhile, Xi Jinping, general secretary of the CCPCC and Chinese president, has advanced a ‘holistic view of national security,’ encompassing 11 broad areas of national security concerns—from political, homeland, military, economic, cultural, social,
technological, information, ecological, resource, to nuclear.28 In the 12th meeting of the Central Committee for Comprehensive Deepening Reform, held on February 14, 2020, Xi highlighted the need to incorporate biosafety/biosecurity into his ‘holistic view’ by systematically planning the construction of national biosafety/biosecurity risk prevention and control systems and comprehensively improving national biosafety/biosecurity governance capabilities.29 Xi’s remark implies his awareness of the seriousness of China’s biosafety/biosecurity challenges on one hand and his realization of the need for relevant legislations in China on the other. Given the top–down and sometimes politics-driven nature of lawmaking in China, Xi’s political commitment has set the tone for the recent acceleration on the Biosafety/Biosecurity Law.

Although China’s biosafety/biosecurity legislative process started before Xi Jinping’s recent remark, as noted, the global COVID-19 pandemic added a further sense of urgency.30 Conspiracy theories concerning the origin of COVID-19 have abounded. But concerns about the safety of laboratories handling a highly contagious virus and the possibility of the virus jumping from wildlife to humans via bats are real and having a clear perspective of biosafety/biosecurity governance. 31

III. LEGISLATIVE PROGRESS

China has engaged in policy and regulatory learning through actively participating in international conventions and treaties pertaining to biosafety/biosecurity. China is a party to the major international agreements regulating biological weapons, having acceded to the Geneva Protocol in 1952 and the BWC in 1984; China joined the CBD in 1992 and ratified the Cartagena Protocol on Biosafety in 2000; and China also ratified the International Convention for the Protection of New Varieties of Plants in 2004 and the International Plant Protection Convention in 2005.32 Such experience has incentivized China to harmonize domestic laws, regulations, norms, and statutes with international ones and to make domestic legislations in line with both its own legislative procedures and its international responsibilities and obligations.

China introduced legislations on biosafety/biosecurity much later than developed countries. In fact, many of the country’s biosafety/biosecurity-related laws and regulations were promulgated in the 1980s to promote the development of biotechnology.33 Since the 1990s China has stepped up regulatory efforts to promote biosafety if not

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28 David M. Lampton, Xi Jinping and the National Security Commission: Policy Coordination and Political Power, 24 J. CONTEMP. CHINA 759–777 (2015).
29 Phoebe Zhang and Simone McCarthy, Coronavirus: Xi Jinping Calls for Overhaul of China’s Health Crisis Response System, SOUTH CHINA MORNING POST, Feb. 14, 2020.
30 Xiaoli Wang, Enhancing the National Biosecurity System in China amidst COVID-19 Epidemic. 2(1) JOURNAL OF BIOSAFETY AND BIOSECURITY 3–4 (2020).
31 Kristian G. Andersen, Andrew Rambaut, W. Ian Lipkin, Edward C. Holmes, and Robert F. Garry, The Proximal Origin of SARS-CoV-2, 26 NATURE MEDICINE 450–452 (2020); Mary Van Beusekom, Scientists: ‘Exactly Zero’ Evidence COVID-19 Came from a Lab (Center for Infectious Disease Research and Policy, University of Minnesota, 2020), https://www.cidrap.umn.edu/news-perspective/2020/05/scientists-exactly-zero-evidence-covid-19-came-lab (accessed July 20, 2020).
32 Wang, supra note 2.
33 Cao, supra note 22.
Table 2. China’s existing laws, regulations, and measures related to biosafety/biosecurity

| General                                                                 |                                     |                                     | Pathogenic microorganisms          |                                     |                                     | Laboratory biosafety                                                                 |
|------------------------------------------------------------------------|--------------------------------------|--------------------------------------|------------------------------------|------------------------------------|-----------------------------------|------------------------------------------------------------------------------------|
| Criminal Law (NPC, 1979; most recent amendment, 2021)                  |                                     |                                     | Measures on the Preservation of Medical Microorganisms in China (Ministry of Health, 1985)*** |                                     | Regulations on the Administration of International Deposit of Microorganisms in China (State Science and Technology Commission, 1986)*** | Regulations on the Management of Biosafety of Pathogenic Microorganism Laboratories (State Council, 2004; second amendment, 2018)** |
| Constitution (NPC, 1982; most recent amendment, 2018)                 |                                     |                                     | Regulations on the Administration of International Deposit of Microorganisms in China (State Science and Technology Commission, 1986)*** |                                     | Pathogenic Microorganisms (Ministry of Health, 2005)***                             | Interim Measures for the Management of Infectious SARS Virus Research Laboratories (Ministry of Science and Technology, Ministry of Health, State Food and Drug Administration, and State Environmental Protection Administration, 2003)*** |
| National Security Law (NPC Standing Committee, 2015)                  |                                     |                                     | Categorized List of Animal Pathogenic Microorganisms (Ministry of Agriculture, 2005)*** |                                     |                                    | Measures for the Approval of Biosafety Management of Highly Pathogenic Microorganism Laboratory for Animal Pathogens (Ministry of Agriculture, 2005)*** |
| Anti-Terrorism Law (NPC Standing Committee, 2015; second amendment, 2018) |                                     |                                     | List of Human-Infecting Pathogenic Microorganisms (Ministry of Health, 2006)*** |                                     |                                    | Laboratories and Experimental Activities (Ministry of Health, 2006; amendment, 2016)*** |
| Biosafety/Biosecurity Law (NPC Standing Committee, 2020)              |                                     |                                     | Regulations on the Transportation of the Species or Samples of Highly Human-Infecting Measures for the Preservation of the Species of Animal Pathogenic Microorganisms (Ministry of Agriculture, 2006)*** |                                     |                                    | Measures for the Biosafety and Environment Management of Pathogenic Microorganism Laboratories (State Environmental Protection Administration, 2006)*** |
| Regulations on the Safety in Biotechnology Research and Development (Ministry of Science and Technology, 2017)*** |                                     |                                     |                                    |                                     |                                    | Measures for the Review of the Construction of High-Level Pathogenic Microorganism Laboratories (Ministry of Science and Technology, 2011; amendment, 2018)*** |
|                                                                        |                                     |                                     |                                    |                                     |                                    | Measures for the Biosafety Approval of Highly Human-to-Human Pathogenic Microorganism |

(Continued)
### In Table 2. Continue

Guiding Opinions on Strengthening the Biosafety Management of High-Grade COVID-19 Microorganism Laboratories (Ministry of Science and Technology, 2020)***

#### Infectious diseases

- Border Health and Quarantine Law (NPC Standing Committee, 1986, third amendment, 2018)*
- Law on the Prevention and Control of Infectious Diseases (NPC Standing Committee, 1989; second amendment, 2013)*
- Measures for the Implementation of the Law on the Prevention and Control of Infectious Diseases (State Council, 1991)**
- Regulations on Domestic Traffic Sanitation and Quarantine (State Council, 1998)**
- Regulations on Domestic Traffic Health Quarantine (State Council, 1998)**
- Regulations on the Prevention and Control of AIDS (State Council, 2006)**
- Measures for the Implementation of the Regulations on Domestic Traffic Health Quarantine (Ministry of Health, 1999)***
- Measures for the Prevention and Treatment of Infectious SARS (Ministry of Health, 2003)***
- Measures for the Pre-examination and Triage of Infectious Diseases in Medical Institutions (Ministry of Health, 2005)***
- Regulations on the Autopsy of the Corpses of Patients with Infectious Diseases or Suspected Infectious Diseases (Ministry of Health, 2005)***

#### Genetic engineering and genetic modification

- Regulations on the Biosafety Management of Agricultural GMOs (State Council, 2001; second amendment, 2017)**
- Measures for the Management of Genetic Engineering Safety (State Science and Technology Commission, 1993)***
- Measures for the Biosafety Management of Agricultural GMOs (Ministry of Agriculture, 2002; second amendment, 2017)***
- Measures for the Management of the Biosafety Evaluation of Agricultural GMOs (Ministry of Agriculture, 2002; third amendment, 2017)***
- Measures for the Labeling Management of Agricultural GMOs (Ministry of Agriculture, 2002; second amendment, 2017)***
- Measures for the Examination and Approval of Processing of Agricultural GMOs (Ministry of Agriculture, 2006)***
- Regulations on the Production and Operation Licensing of Genetically Modified Cotton Seeds (Ministry of Agriculture, 2016)***
- Measures for the Administration of Examination and Approval of the Development of Forest Transgenic Engineering Activities (State Forestry Administration, 2018)***

#### Food safety

- Food Safety Law (NPC Standing Committee, 2009; second amendment, 2018)*
- Regulations on the Implementation of the Food Safety Law (State Council, 2009; amendment, 2016)**
- Administrative Measures for New Resource Foods (Ministry of Health, 2007)***

(Continued)
Table 2. Continue

| Category                           | Regulations/Measures                                                                 |
|-----------------------------------|-------------------------------------------------------------------------------------|
| Measures for the Management of New Varieties of Food Additives (Ministry of Health, 2010)*** |                                                                                      |
| Regulations on the Application and Acceptance of New Varieties of Food Additives (Ministry of Health, 2010)*** |                                                                                      |
| Measures for the Management of the National Food Safety Standards (Ministry of Health, 2010)*** |                                                                                      |
| Measures for the Management of the Safety Review of New Food Raw Materials (National Health and Family Planning Commission, 2013; amendment, 2017)*** |                                                                                      |
| **Biological products**           |                                                                                      |
| Regulations on the Administration of Blood Products (State Council, 1996; amendment, 2016)** |                                                                                      |
| Regulations on the Administration of Vaccine Circulation and Vaccination (State Council, 2005; amendment, 2016)** |                                                                                      |
| Measures for the Management of the Issuance of Biological Products (State Food and Drug Administration, 2017)*** |                                                                                      |
| **Genetic resources and bioresources** |                                                                                      |
| Ocean and Environment Protection Law (NPC Standing Committee, 1982; third amendment, 2017)* |                                                                                      |
| Grassland Law (NPC Standing Committee, 1986; amendment, 2002)* |                                                                                      |
| Wildlife Protection Law (NPC Standing Committee, 1988; most recent amendment, 2018)* |                                                                                      |
| Environmental Protection Law (NPC Standing Committee, 1989; amendment, 2014)* |                                                                                      |
| Livestock Law (NPC Standing Committee, 2005; amendment 2015)* |                                                                                      |
| Regulations on Nature Reserves (State Council, 1994; second amendment, 2017)** |                                                                                      |
| Regulations on the Protection of Wild Plants (State Council, 1996; amendment, 2017)** |                                                                                      |
| Measures for the Examination and Approval of Entry and Exit of Livestock and Poultry Genetic Resources and International Cooperation in Research and Utilization (State Council, 2008)** |                                                                                      |
| Regulations on the Implementation of the Protection of Terrestrial Wild Animals (State Forestry Administration, 1992; second amendment, 2016)*** |                                                                                      |
| Regulations on the Administration of Experimental Animals (State Science and Technology Commission, 1988; third amendment, 2017)*** |                                                                                      |
| Regulations on the Administration of Human Genetic Resources (State Council, 2019)** |                                                                                      |
| **Research ethics**               |                                                                                      |
| Ethical Principles Guiding Human Embryonic Stem Cell Research (Ministry of Science and Technology and Ministry of Health, 2003)*** |                                                                                      |
| Guiding Opinions on Treating Experimental Animals (Ministry of Science and Technology, 2006)*** |                                                                                      |
| Ethical Review Methods for Human Biomedical Research (National Health and Family Planning Commission, 2016)*** |                                                                                      |

(Continued)
Table 2. Continue

**Dual-use items and technologies**
Customs Law (NPC Standing Committee, 1987; most recent amendment, 2017)*
Regulations on the Export Control of Dual-Use Biological Products and Related Equipment and Technologies (State Council, 2002)**
Measures for the Management of Import and Export Licenses of Dual-Use Items and Technologies (Ministry of Commerce and General Administration of Customs, 2005)***
Measures for the Management of General Licenses for the Export of Dual-Use Items and Technologies (Ministry of Commerce, 2009)***

**Animal and plant quarantine**
Law on Animal Epidemic Prevention (NPC Standing Committee, 1986; most recent amendment, 2021)*
Regulations on Plant Quarantine (State Council, 1983; second amendment, 2017)**
Details on the Implementation of the Regulations on Plant Quarantine (Agriculture) (Ministry of Agriculture, 1995; third amendment, 2007)***
Standards of the Management of National Animal Epidemic Situation Forecasting and Reporting System (Trial) (Ministry of Agriculture, 2002)***
Measures for the Management of Animal Quarantine (Ministry of Agriculture, 2010)***
Measures for the Review of Animal Epidemic Preventions (Ministry of Agriculture, 2010)***
Regulations on the Evaluation and Management of Areas of No Prescribed Animal Epidemics (Ministry of Agriculture, 2017)***
Measures for the Management of the Reporting and Release of Agricultural Plant Epidemics (Ministry of Agriculture, 2010)***

**Entry and exit inspection and quarantine**
Law on Border Health and Quarantine (NPC Standing Committee, 1986; third amendment, 2018)*
Law on the Entry and Exit Animal and Plant Quarantine (NPC Standing Committee, 1991; amendment, 2009)*
Regulations on the Implementation of the Entry and Exit Animal and Plant Quarantine (State Council, 1996)**
Measures for the Health Supervision at Border Ports (Ministry of Health, Ministry of Communications, General Administration of Civil Aviation of China, Ministry of Railways, 1982; first amendment, 2011)***
Details on the Implementation of the Law on Border Health and Quarantine (Ministry of Health, 1989; second amendment, 2016)***
Measures for the Management of Sealing and Marking of the Entry and Exit Animal and Plant Quarantine (Ministry of Agriculture, 1998)***
Measures for the Management of Examination and Approval of Entry Animal and Plant Quarantine (General Administration of Quality Supervision, Inspection and Quarantine, 2002; second amendment, 2018)***
Regulations on the Administration of the Risk Analysis of Incoming Animals and Animal Products (General Administration of Quality Supervision, Inspection and Quarantine, 2002; amendment, 2018)***

(Continued)
Table 2. Continue

Measures on the Management of the Entry and Exit GMO Product Inspection and Quarantine (General Administration of Quality Supervision, Inspection and Quarantine, 2004; second amendment, 2018)***

Measures for the Management of the Approval of Species and Quantity of Introduced Alien Species of Terrestrial Wildlife (State Forestry Administration, 2005; second amendment, 2016)***

Measures for the Management of Quarantine of Products Carried by the Entry and Exit Persons (General Administration of Quality Supervision, Inspection and Quarantine, 2012)***

Measures for the Management of the Inspection and Quarantine of Entry and Exit Non-food Animal Products (General Administration of Quality Supervision, Inspection and Quarantine, 2014)***

Regulations on the Administration of the Health and Quarantine of Entry and Exit Special Items (General Administration of Quality Supervision, Inspection and Quarantine, 2015)***

Measures for Inspection and Quarantine of Entry-Exit Grain (General Administration of Quality Supervision, Inspection and Quarantine, 2016)***

Measures for the Management of the Quarantine of Genetic Materials for Entry Animals (General Administration of Quality Supervision, Inspection and Quarantine, 2003; second amendment, 2018)***

Unexpected safety emergencies

Emergency Response Law (NPC Standing Committee, 2007)*

Regulations on Public Health Emergencies (State Council, 2003; amendment, 2011)**

Regulations on Emergency Responses to Major Animal Epidemics (State Council, 2005; amendment, 2017)**

National Emergency Plan for Public Health Emergencies (State Council, 2006)**

National Emergency Plan for Medical and Health Rescue of Public Emergencies (State Council, 2006)**

National Emergency Plan for Responses to Major Animal Epidemics (State Council, 2006)**

Measures for the Management of the Monitoring and Information Reports of Public Health Emergencies and Infectious Disease Epidemics (Ministry of Health, 2003; amendment, 2006)***

Regulations on the Traffic Emergency during Public Health Emergencies (Ministry of Health, 2004)***

Measures for the Handling of Unexpected Forestry Pest Incidents (State Forestry Administration, 2005; amendment, 2015)***

Sources: Deqiao Tian and Bing lu (Comps.), Collection of laws, Regulations, and Standards of the People’s Republic of China on Biosafety and Biosecurity (in Chinese) (Beijing: Law Press, 2017); China National Center For Biotechnology Development, A Compilation of Laws and Regulations of the People’s Republic of China on Biosafety and Biosecurity (in Chinese) (Beijing: Scientific and Technical Documentation Press, 2019); Huigang Liang, Xiang Xiaowei, Ma Haixia, and Yuan Zhiming, History of and Suggestions for China’s Biosafety Legislation, 1 Journal of Biosafety and Biosecurity 134–139 (2019); Yan Zhang and Min Ma, Biosafety/Biosecurity Legislation in China: Reflection and Improvement (in Chinese), 12 Journal of Engineering Studies 84–91 (2020).

Notes: *law; **regulation; ***ministerial measure. Names of government agencies are those used at the time of issuing laws, regulations, and measures.
biosecurity. And the government has made a new wave of legislative efforts in the past or so decade (Table 2).34

The current laws, regulations, and measures cover a wide range of biosafety/biosecurity issues. To start with, there are the Food Safety Law, Grassland Law, Wildlife Protection Law, Environmental Protection Law, and related implementation regulations and measures. As concerns about biosafety/biosecurity, especially those about the prevention and control of infectious diseases in the aftermath of SARS, gained urgency, China has greatly improved its capabilities of responding to emerging infectious diseases and safeguarding biosafety/biosecurity by amending such laws as the Border Health and Quarantine Law and the Law on the Prevention and Control of Infectious Diseases, Emergency Response Law, among others. Given that the SARS outbreak showed greatest risks of viruses jumping from animals to human, China amended the Wildlife Protection Law, the Law on Quarantine of Entry and Exit of Animals and Plants, and the Law on Animal Epidemic Prevention.

The SARS outbreak also has stimulated China’s enthusiasm to build more high-level biosafety laboratories that enable its scientists to carefully handle dangerous pathogens and effectively prevent and control severe and emerging infectious diseases. Currently, China has 48 biosafety level (BSL)-3 laboratories and its first BSL-4 lab, located at the Institute of Virology, Chinese Academy of Sciences, in Wuhan, began operations in 2015.35 And the 2016 High-Level Biosafety Laboratory System Construction Plan stipulates that by 2025 China should have had a national system of higher BSL laboratories, including five to seven BSL-4 laboratories, reasonably distributed and operated.36 Therefore, China, like other countries, has introduced and implemented relevant regulations on the safety and security of these laboratories through enhancing personnel training, conducting scientific research, and assessing possible risks.37 One of the most significant legislations is the Regulations on the Management of Biosafety of Pathogenic Microorganism Laboratories, issued by the State Council, China’s cabinet, in 2004 and amended in 2018. Consequently, LAI accidents did not happen during China’s responses to the Ebola epidemic in West Africa38 and during the COVID-

34 Deqiao Tian and Bing Lu (Comps.), Collection of Laws, Regulations, and Standards of the People’s Republic of China on Biosafety and Biosecurity (in Chinese) (Beijing: Law Press, 2017); China National Center for Biotechnology Development, A Compilation of Laws and Regulations of the People’s Republic of China on Biosafety and Biosecurity (in Chinese) (Beijing: Scientific and Technical Documentation Press, 2019); Rui He, Jin-qiang Tian, Zi-qi Pan, and Lian-qi Zhang, Laws and Regulations for Biosafety in China: Status and Prospect (in Chinese), 40 ACADEM. J. MIL. MED. 937–944 (2019); Huigang Liang, Xiang Xiaowei, Ma Haixia, and Yuan Zhiming, History of and Suggestions for China’s Biosafety Legislation, 1 J. BIOSAF. BIOSECUR. 134–139 (2019); Yan Zhang and Min Ma, Biosafety/Biosecurity Legislation in China: Reflection and Improvement (in Chinese), 12 J. ENG. STUD. 84–91 (2020).
35 David Cyranoski, Inside China’s Pathogen Lab, 542 NATURE 399–400 (2017); Lifei Feng, Biosafety: Build a ‘Great Wall’ (in Chinese), SCIENCE TIMES, May 29, 2020.
36 Gao, supra note 19; Feng, supra note 34.
37 W. Feng, Haixia M, Aimei Deng, Zong Sheng C, Zhiming Y, Studies on Developing a Safe-Management Standard System for Chinese Biosafety Laboratories, 1 J. BIOSAF. BIOSECUR. 39–45 (2019); Guizhen Wu, Laboratory Biosafety in China: Past, Present, and Future, 1 BIOSAF. HEALTH 56–58 (2019); Zhiming Yuan, Current Status and Future Challenges of High-Level Biosafety Laboratories in China, 1 J. BIOSAF. BIOSECUR. 123–127 (2019); Rebecca L. Moritz, Kavita M. Berger, Barbara R. Owen, and David R. Gillum, Promoting Biosecurity by Professionalizing Biosafety, 367 SCIENCE 856–858 (2020).
38 Wu, supra note 36.
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19 epidemic; nor is there scientific evidence to support conspiracy theories that the coronavirus escaped from the BSL-4 lab in Wuhan.39

Entering 2020, China’s NPC has planned to enact and amend 17 laws and regulations, some of which are related to health security.40 As there was possible association between the COVID-19 outbreak and one of China’s many wildlife food markets, in January 2020, the State Administration for Market Regulation (SAMR), the Ministry of Agriculture and Rural Affairs (MOARA), and the National Forestry and Grassland Administration announced to ban all trading of wild animals at markets and restaurants and on e-commerce platforms. A month later, the NPC Standing Committee passed the Decision on Comprehensively Prohibition of Illegal Trade of Wild Animals, aimed at eradicating the abuse of wild animals and effectively guaranteeing people’s lives and health, restricting wildlife trade, and banning the consumption of bushmeat and market sales of farmed wild animals. Also under amendment are the Wildlife Protection Law, the Law on Animal Epidemic Prevention, the Border Health and Quarantine Law, the Emergency Response Law, the Law on the Entry and Exit Animal and Plant Quarantine, as well as the Law on the Prevention and Control of Infectious Diseases. The most important is no doubt to enact the Biosafety/Biosecurity Law.

Altogether, the existing laws, regulations, and measures (see Table 2), along with those in the legislative pipeline, form a comprehensive legal biosafety/biosecurity legislative and regulatory regime. However, such a regime is far from rising to the mounting challenges. First, China needs a specific piece of legislation pertaining to biosafety/biosecurity whose enactment is said to be not easy.41 The missing of such an overarching and critical piece of legislation has handicapped China’s efforts to develop biotechnology and the life sciences. The existing laws and regulations also are not applicable to emerging biosecurity issues such as dealing with the risks arising from the dual-use technologies and gain-of-function research and appropriately managing human genetic resources and bioresources, among others.

Second, despite their overwhelming number, relevant legislations, including the Constitution, Criminal Law, National Security Law, Anti-Terrorism Law, and other laws and regulations, tend to be ‘general and non-specific in most cases’ to biosafety and biosecurity.42 For example, although it stipulates the prevention and control of infectious diseases, biological invasions, and bioterrorism and the prevention and control and bioresource conservation, the Criminal Law may not be able to deter and investigate wrongdoing and pursue related responsible parties accordingly.43 The proliferation of laws and regulations has made it difficult to maintain a delicate balance between their specificity and excessive generality. In fact, such problems have persisted, caused in large part by China’s ‘relatively closed nature, limited capacity and inexpe-

39 Andersen et al., supra note 30; Van Beusekom, supra note 30.
40 National People’s Congress, Legislation and Law Amendment Work Plan of the 13th National People’s Congress Standing Committee on Strengthening the Rule of Law in Public Health (in Chinese), http://www.npc.gov.cn/npc/c30834/202004/eaec363c350473f9c2877237687c61c.shtml (accessed Mar. 1, 2021).
41 Qin Qin and Youhai Sun, A Global Biosafety Strategy Research Framework with Specific Implications for China, 1 J. BIOSAF. BIOSECUR. 105–112 (2019).
42 Liang et al., supra note 33 at 135.
43 He et al., supra note 33; Zhang and Ma, supra note 33.
identify and remedy such problems in the drafting process.\textsuperscript{44} China as a latecomer and follower in various legislations also may have exacerbated the problems.

Third, laws, regulations, and measures are always reactive rather than proactive, with the biosafety/biosecurity legislations no exception.\textsuperscript{45} Laws and regulations are not sophisticated and delicate and contain principles but not necessary and detailed provisions so as to cause problems in implementation. Consequently, the Chinese lawmakers have to amend them frequently. And last, laws and regulations do not appear to be mounting sufficiently coordinated efforts in formulation and especially in implementation.\textsuperscript{46}

China’s development of a GMO biosafety regulatory regime illustrates many of the problems identified here.\textsuperscript{47} In 1993, the State Science and Technology Commission, the predecessor of the Ministry of Science and Technology (MOST), followed international experiences to come up with regulations to support the development of biotechnology. Such regulations mostly dealt with biosafety issues relating to scientific research, from risk assessment, biosafety application and approval processes, control principles, and legal responsibilities. Then, the Ministry of Agriculture (MOA), the predecessor of the MOARA, got involved with formulating procedures for research, field tests, and commercialization of GM crops. Symbolically, these two government agencies initiated a process of the establishment of China’s biosafety regulatory regime. But it is until 2001 that the State Council stepped in with high-level legislations. At one time China was expected to enact a biosafety law in October 2003,\textsuperscript{48} which, in fact, had not been materialized until 2018 when the NPC Standing Committee formally put the lawmaking on its legislative agenda.

The operation of China’s GMO biosafety regulatory regime involved many government agencies. At the highest level was the Joint Ministerial Conference (JMC), a mechanism within the State Council responsible for overall policymaking, administration, and coordination pertaining to GMO biosafety. Convened by the minister of agriculture and rural affairs once a year, the JMC consisted of ministers or vice ministers from several government agencies within the State Council—the National Development and Reform Commission, the National Health Commission (NHC), the ministries of science and technology, education, finance, commerce, and ecology and environment (MOEE), the SAMR, and the National Medical Products Administration.

Then the MOARA led the biosafety regulation by functionally carrying out nationwide oversight and inspection of biosafety involving agricultural GMOs through an Office of Agricultural Genetic Engineering Biosafety Administration that handles day-to-day operations and routine matters and a National Biosafety Committee on Agricultural Genetically Modified Organisms that oversees research and commercialization activities in agricultural GMOs. The NHC was in charge of safety management of GM

\textsuperscript{44} Claudia Ross and Lester Ross, \textit{Language and Law: Sources of Systemic Vagueness and Ambiguous Authority in Chinese Statutory Language}, in \textit{The Limits of the Rule of Law in China}, Karen G. Turner, James V. Feinerman, and R. Kent Guy ed. (Seattle, WA: University of Washington Press, 2000), at 223.

\textsuperscript{45} The ‘reactive nature’ of biosecurity legislation also exists in the U.S., see Berger et al., supra note 16.

\textsuperscript{46} Huang, supra note 27.

\textsuperscript{47} Cao, supra note 22, in chapter 4.

\textsuperscript{48} James Keeley, \textit{Regulating Biotechnology in China: The Politics of Biosafety}, IDS Working Paper 208 (Brighton, Sussex: Institute of Development Studies, 2003), at 8–9.
foods by assembling experts on food safety, nutrition, and toxicology at the Chinese CDC to review and assess GM crops and foods whereas the SAMR had the mandate of safety management of food production and marketing, including labeling of GM foods, and the was General Administration for Quality Supervision, Inspection and Quarantine responsible for safety issues related to imports and exports of GM foods. Finally, given its representation of China in the international negotiation on the CBD and the Cartagena Protocol on Biosafety, the MOEE was also actively and aggressively involved in the risk assessment of GMOs and indeed was in charge of drafting the now-defunct GMO-oriented biosafety law.

Such a description seems to suggest that China’s GMO biosafety regulatory regime mostly operated at ministerial levels. The MOA minister, who coordinated the JMC, was just an average minister among many equals so that he did not possess enough administrative power. Each ministry would bring its own interests into the JMC that would run into difficulties formulating and implementing regulations and measures and whose mechanism would fall apart if efforts at participating ministries were not properly coordinated. Inevitably, there existed legislative gaps, conflicts, and inconsistencies, as well as ineffective law enforcement.49

It is against such a backdrop that China felt it necessary to formulate a comprehensive law that makes systematic institutional arrangements, construction, and innovations for the protection of its biosafety/biosecurity.

IV. A READING OF THE BIOSAFETY/BIOSECURITY LAW

The law has been formulated to serve both domestic and international purposes. Domestically, it delineates strategic objectives of fitting biosafety/biosecurity into Xi Jinping’s ‘holistic view of national security’ and promoting the harmony between human and nature, or ecological civilization, one of Xi’s favorable terms. It also converges with international norms in biosafety/biosecurity, thus facilitating China’s implementation of relevant international treaties and international exchanges and cooperation.

In particular, the Biosafety/Biosecurity Law defines biosafety/biosecurity as ‘a country’s capacities of effectively preventing and responding to the dangerous threats of biological agents and related factors so as to maintain stable and healthy development of biotechnology, to affirm a status of less danger and threats to the lives and health of people and ecosystem, and to ensure national security and sustainable development.’ Apparently, such a definition is not completely consistent with the definition of biosafety or the definition of biosecurity discussed at the onset of the paper. Or, the law uses ‘shengwuanquan’ in the name but covers both ‘shengwuanquan’ and ‘shengwu anbao’ in terms of content. The law also focuses on protecting the safety and security of China’s bioresources, promoting and safeguarding the development of biotechnology, and preventing and prohibiting the use of biological agents or biotechnology for the purpose of harming national security. To fulfill these objectives, it has 88 articles in 10 chapters stipulating regulations in five broad categories:

49 Chang Jiwen and Wenzuan Yu, Establishing an Institutionalized Countermeasure for Biosafety/Biosecurity and Accelerating the Legislative Process of the Biosafety/Biosecurity Law (in Chinese), https://www.sohu.com/a/385102376_619341 (accessed July 20, 2020).
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- Preventing and controlling major emerging infectious diseases and animal and plant epidemics;
- Managing research, development, and application of biotechnology;
- Ensuring biosafety in laboratories;
- Ensuring the security of human genetic resources and bioresources; and
- Preventing bioterrorism attacks and defending against the threat of biological weapons.⁵⁰

The law stipulates that its comprehensive implementation need to emphasize the principles of risk prevention and prudent development through establishing national systems, covering 11 biosafety/biosecurity-related aspects from monitoring and early warning; risk investigation and assessment; information sharing; information disclosure; catalogs and lists; standards; reviews; emergency responses; investigation and source tracing for incidents; entry approval; to responses to major overseas incidents. Although confining its geographical scope to China’s sovereign jurisdiction, the law has implications beyond the Chinese territory. For example, the law stipulates that approval be needed for foreign investment in the establishment of pathogenic microbial laboratories and for acquisition and utilization of indigenous bioresources; it also prohibits foreign organizations, individuals, and their China-based entities from harvesting and preserving human genetic resources in China.

One of the notable and innovative features of the law is its attention devoted to the strengthening of the nation’s biosafety/biosecurity capacities. Indeed, the implementation of biosafety/biosecurity measures relevant to biological research and products, the management of bioresources and human genetic resources, dual-use biotechnology and its control, animal and plant quarantine, entry–exit inspection and quarantine, emergency incident response, and ethical management require the possession of capabilities in preventing, protecting, and mitigating the risks that may endanger China’s biosafety/biosecurity. Doing so needs not only financial resources but also policy support for biosafety/biosecurity governance through increasing funding, infrastructure construction, talent training, encouraging and supporting indigenous research and innovation, and the development of technologies and industry.

Nevertheless, there is still room for improvement for the law. First, while having a fairly comprehensive and systematic coverage, the law itself is short of detailed provisions, a long existing problem. And stipulations are vague on the relationship between the new law and related special legislations such as the prevention and control of infectious diseases; live animals and plants; biodiversity and ecological protection; food safety; animal and plant inspection and quarantine, among others.⁵¹ Are they complementary or supplementary? The relationship between biosafety/biosecurity measures and the protection of live products, for example, involves regulating the introduction of alien species. Regarding the research and commercialization of biotechnology, presumably the law overwrites those existing regulations and measures; but the law says little of how. Different norms can be adopted to resolve these issues. For

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⁵⁰ The law claims to be applicable to preventing the invasion of alien species and protecting biodiversity and dealing with microbial drug resistance but does not have separate chapters on them.

⁵¹ Chang Jiwen, Accelerate the Establishment of a National Biosafety/Biosecurity Legal and Regulatory System (in Chinese), STUDY TIMES, Feb. 17, 2020, at 1.
example, if there are provisions in the existing laws, the Biosafety/Biosecurity Law needs to consider making the entire legislative regime more cohesive; in areas that the current laws have no provisions, obviously the Biosafety/Biosecurity Law takes over. There is similar need to deal with the relationship between the law and State Council regulations and ministerial measures as well.

Second, given the involvement of quite a number of ministries under the State Council—NHC, MOARA, MOST, the Ministry of Foreign Affairs, and military apparatuses—in the implementation, the law campaigns for a coordination mechanism, one that is similar to China’s biosafety administration of GMOs but at a higher level, involving more bureaucracies. Such a mechanism would be responsible for analyzing and judging the national biosafety/biosecurity situation, organizing, coordinating, supervising, and promoting national biosafety/biosecurity-related work. But the questions lie in what lessons China has learned from its previous practice of the GMO biosafety regulatory mechanism and especially how effective and efficient such an institutional arrangement had been in addressing various issues arising from GMO research and commercialization. As the coverage of the Biosafety/Biosecurity Law is much wider and the national security emphasized, China may have to consider instead having a permanent government body that functions as an intergovernment coordinator and resolves disputes between government agencies. In the case of food safety, in 2010, following the passage of the Food Safety Law, the State Council established a high-level regulatory body, the National Food Safety Commission, headed by the first vice-premier, as an overarching, supraministry food safety watchdog to centralize and consolidate the management of food safety and a coordinator of various related regulatory functions. In terms of coordination, China’s NHC, MOST, Ministry of Industry and Information Technology, SAMR, and NMPA jointly issued the General Requirements for the Biosafety of Vaccine Production Facilities as a temporary emergency standard to promote the production of vaccines for COVID-19. Apparently, at least equally important, biosafety/biosecurity involves multiple and vast bureaucracies, policy coordination and implementation are tremendously challenging so that innovation is necessary to simplify chains of command and reduce bureaucratic stovepiping.

Third, the liability and punishment for violation are not always clearly defined in China’s legislations. Likewise, the Biosafety/Biosecurity Law does not explicitly address administrative, criminal, and civil responsibilities for violation of its different provisions, although it specifies monetary penalties for such violation. But there is a need to establish an institutional mechanism that is able to remediate and compensate for accidental and intentional damages to public health and safety, the ecological environment, and biodiversity.

Fourth, the law needs to make provisions available on the supervision of research carried out using modern biotechnology such as embryo transfer, genetic modification, and gene editing to prevent scandals such as gene-edited babies from happening. Sometimes the relationship between the development of biotechnology, especially the dual-use ones, and biosafety/biosecurity is irreconcilable while lawmaking is often

52 Wai-Hang Yee and Peng Liu, *Control, Coordination, and Capacity: Deficits in China’s Frontline Regulatory System for Food Safety*, 29 J. CONTEMP. CHINA 503–518 (2020).

53 Alice Yan, *China Sets Biosafety Standards for Coronavirus Vaccine Makers*, *South China Morning Post*, June 19, 2020.
lagging, how to prioritize one over the other is challenging. As the risk incurred in embryo transfer and gene editing differs from that of laboratory leaks with the former also invoking bioethics concerns, calls for different legislations are also warrant.

Finally, provisions about GMOs are conspicuously missing in the Biosafety/Biosecurity Law, although GMOs are an area with significant biosafety and biosecurity concerns. One possible explanation is the inclusion of GMOs would make the law cumbersome and controversial. However, would having two sets of legislations dealing with virtually similar biosafety/biosecurity issues make the implementation of both legislations more complicated and problematic?

V. CONCLUSION AND DISCUSSIONS
Some 40 years ago, a biosafety regulatory regime started to take shape in China to stimulate the development of genetic engineering and especially agricultural GMOs. But China’s biosafety/biosecurity legislations have evolved to achieve a thoughtful balance between developing biotechnology and the life sciences, protecting human health and the environment, and aligning its domestic laws and regulations with international norms and standards. The promulgation of the Biosafety/Biosecurity Law was much delayed until 2018 when the Chinese government and legislature finally put it on their agenda. The enactment of the law shows Chinese government’s strong commitment to refining its biosafety/biosecurity governance. This is a positive development insofar as the law fills gaps where the existing statutes may have been too general.

The law clearly delineates maintaining biosafety/biosecurity and harmonious coexistence of human and nature as its overall requirement and elevates biosafety/biosecurity to the level of national security. Indeed, biosafety/biosecurity is entwined with concerns about a country’s national security in a rapidly changing world and the Chinese leader Xi Jinping has called for the inclusion of biosafety/biosecurity into his ‘holistic view of national security.’ The law covers a wide range of biosafety/biosecurity issues, setting up main tasks such as the safeguarding of health and lives of people and ecosystem, the protection of genetic resources and bioresources, the promotion of the healthy development of biotechnology, and the prevention of biological threats. The timing of the legislation also coincided with the rise of global epidemics of infectious diseases, microbial resistance, biological invasion and loss of biodiversity, loss and piracy of genetic resources, laboratory safety, misuse of biotechnology, threats of biological weapons, and bioterrorism. As a whole, China’s Biosafety/Biosecurity Law not only meets but also overlaps with or exceeds the legislative objectives of its existing ecological and environmental protection laws. In fact, such a Chinese legislative approach also leads the world. Going forward, China, as many countries in the world, is facing the risks and threats from both outside and inside of the country such as rising global population, looming climate change, rapid technological change, and economic transformation. China also needs to cooperate with other countries in dealing with biosafety/biosecurity challenges.

By enacting the Biosafety/Biosecurity Law, China is making an urgent strategic choice to enhance the nation’s biosafety/biosecurity governance capabilities. However, having a law is one thing, having the law fully implemented and enforced is quite another. Efforts need to be escalated in several areas. The implementation of the law involves the cooperation, coordination, and communication between various
government ministries. More importantly, the legislature and government need to sort out its relationship with the existing laws, regulations, and measures and streamline them while avoiding redundancy caused by excessive legislations. Accordingly, the NPC Standing Committee has taken steps to amend the Criminal Law and the Law on Animal Epidemic Prevention in 2021. The State Council and relevant ministries need authorization to formulate administrative regulations and implementation measures. Increasing public awareness of the danger of unsafety and insecurity also is necessary.

Maintaining biosafety/biosecurity is a societal endeavor. As a multidisciplinary concept, biosafety/biosecurity focuses on keeping various stakeholders—lawmakers, scientists, and the public, among others—secure from the malicious exploration and exploitation of biological knowledge, technologies, and products. Therefore, China still has a long way to go to fulfill its ultimate objective of having a biosafety/biosecurity law that prevents, protects, and mitigates the risks and hazards to people, society, and the environment.

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54 Moritz et al., supra note 36.