

The Legal System of National Biosafety with Chinese Characteristics: the Status Quo and Trends

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Abstract: Deficiencies of system for bio-risk control and governance in China have been revealed under the background of the “gene-edited babies” trial and COVID-19 pandemic. China takes the integration and classification model to formulate a systematic, basic, and comprehensive biosecurity law, which directs and coordinates other laws and regulations, technical specifications, ethical principles and national standards. They will jointly form the legal system of national biosafety with Chinese characteristics in the future. We should adhere to basic principles of risk prevention, public participation, classification management, strict liability, and international cooperation. Guarantee mechanism of capacity for biosafety, mechanism of classified supervision, mechanism of risk monitoring, early warning and emergency response, mechanism of risk management, mechanism of recovery and remedy, mechanism of biosecurity defence, mechanism of legal responsibility and other systems, should be established. The legal system of national biosafety with Chinese characteristics aims at safeguarding national biological sovereignty, biosafety and human health, promoting innovative development of biotechnology and bioindustry, enhancing global government capacity for biosafety.

1. Introduction

After the “gene-edited babies” trial in November 2018, China speeded up to improve the government system of bio-risk. The COVID-19 pandemic, also, accelerated the legislative process of China’s biosafety law. Conspiracy theorists once claimed the virus occurred unnaturally, which were artificially synthesized and deliberately diffused. Some even believe that the virus is a “genetic weapon”.^[1] These rumours have been refuted many times based on science.^[2] On the one hand, biotechnology plays an important role during anti-COVID-19 fight in China. On the other hand, China is accelerating the improvement of national biosafety legal governance mechanism.

Based on the Biosecurity Law, China is endeavouring to construct its own legal system of national biosafety with Chinese characteristics. And the system echoes the legal demand of national biosafety strategy. The Biosecurity Law has been adopted by the Standing Committee of the National People's Congress (and shall come into force on April 15, 2021), but thorough and deeper studies are needed when constructing the concept, content, framework and path of this system.^[3] Starting from current situations and new challenges of China's biosecurity system of risk prevention, control and governance, combined with backgrounds, conditions and trends of China's legal system, this article discusses concepts, goals, principles and paths of the legal system of national biosafety with Chinese characteristics.

2. China's Biosecurity Risk Prevention and Control System Faces Challenges

2.1 China's Current Legal Framework of Biosecurity

Before October 17, 2020, when the Biosecurity Law was adopted, China had preliminarily established a legal governance framework of biosecurity but lack of a comprehensive biosecurity law. Existing laws, regulations, rules, and regulatory documents mainly focus on environmental ecology, animals and plants, natural resources (biodiversity), food and drug safety, quarantine of animals and plants, exit-entry inspection and quarantine, biosecurity of pathogenic microbe laboratories, infectious diseases control and major public health crisis, genetically modified organisms, management of human genetic resource and gene technology. Their contents include technical criteria and ethical guidelines.

2.2 Deficiencies of China's Current Legal System of Biosecurity

COVID-19 pandemic has exposed deficiencies in China's current bio-risk management system and governance capability. For example, at the beginning of this epidemic, scientific assessment of unknown virus is insufficient, and epidemic-related risk communication is half-true or inadequate. Besides, local government failed to take timely and effective measures to prevent and control emergency, missing the best time to control the epidemic. China has taken timely and effective prevention measures countrywide, so that the spread of COVID-19 was quickly controlled. The institutional reason for above problems lies in the imperfection of China's biosecurity legal system. Before the Biosecurity Law was issued, China had preliminarily formed a legal governance framework of biosecurity, while it is not systematic, comprehensive, scientific and coordinated enough.

First, China's regulation system is not perfect. Due to the lack of a special basic law on biosecurity, legislations are relatively scattered and some even conflict, thus there is no organic and unified legal governance system.

Second, there is a vacuum in regulation. China's legislation mainly focus on the protection of environmental ecology and natural resources, infectious diseases control (and response to public health emergencies, biosecurity of pathogenic microbe laboratories, exit-entry inspection and quarantine, inspection and quarantine of import and export commodities, animals and plants, prevention and treatment of livestock and poultry diseases), protection of wild animals and plants, management of food and drug safety, management of genetically modified organisms, genetic resources and gene technology regulation. There is a lack of special legislation to deal with alien species invasion, bioterrorism and emerging biotechnology risks (such as biosynthesis, gene editing, gene driven, gene weapons). Other regulations are also needed. The national standards such as biosecurity assessment are not comprehensive enough.

Third, the content of regulation is uncomplete. Scientific and rational concept of biosafety governance has not been implemented legally, and systems of risk monitor and early warning, risk assessment, risk communication, governance capacity construction and other mechanisms are lacking.

Finally, the regulation work insufficiently. Due to the lack of an authoritative coordination and decision-making institution, there are many relevant departments (including but not limited to environment, natural resources, science and technology, health, agriculture, education, customs and national defence) and their responsibilities and powers are vague. Owing to inherent drawbacks in risk management system, combined with a weak mechanism of legal liability and governments' low initiative for regulation, biosecurity risk control mechanism operates merely passably.

After April 15, 2021, the implementation of the Biosecurity Law, these deficiencies could be made up. However, national biosafety coordination mechanisms are needed, current legislations should be coordinated and connected, classified regulation measures need to be concretized, and the national biosafety legal governance system needs to be reformed.

3. Guidelines, Goals, and Principles of the Construction of the Legal System of National Biosafety

3.1 Guidelines of Construction of the Legal System of National Biosafety

We should understand the political requirements of the legal system of national biosafety with Chinese characteristics from the perspective of the overall national security concept. President Xi Jinping called for an overall national security outlook^[4], which includes many fields such as political security, homeland security, military security, economic security, cultural security, social security, science and technology security, information security, ecological security, resource security, nuclear safety and so on. Article 4 of the Biosecurity Law of the People's Republic of China declares that 'the leadership of the Communist Party of China over national biosafety work shall be adhered to', this is the foundation of the legal system of overall national security.

It is necessary to understand the institutional function of the legal system of national biosafety with Chinese characteristics from the perspective of modernizing China's system and capacity for governance. Biosecurity governance capacity refers to a country's ability to effectively deal with biological threats and risks, involving science and technology, management, legal system and other aspects. The legal policy, organizational system and capacity improvement should be combined organically, and biological risk management and law-based biosecurity minds should be cultivated, the biological risk identification, early warning system and response measures should be available, in order to modernize national biosafety governance capacity.

We should understand the historical logic of the legal system of national biosafety with Chinese characteristics from the perspective of constructing a community with a shared future for mankind. Bio-risk is vulnerable to spread under the globalization trend. Thus, mankind is bound to share weal and woe and the international community is interdependent. Biosecurity government is a global issue, and legal rules of global governance should be improved under the UN system. During the COVID-19 pandemic, China promptly shared its experience and technical plan such as whole genome sequence information of the virus, epidemiological investigation and clinical diagnosis and treatment, and strongly supported the international community as possible. China provides the international community with a model for epidemic control and global biosecurity governance.

3.2 Goals of the Legal System of National Biosafety

The legal system of national biosafety with Chinese characteristics aims at: defending national biological sovereignty, biosecurity and human health, stimulating the innovation and development of biotechnology and bioindustry, promoting global co-governance and common gains, enhancing national biosafety governance capacity. Article 1 of the Biosecurity Law explains it in detail, that is, 'maintaining national security, preventing and responding to biosecurity risks, safeguarding the lives and health of the people, protecting biological resources and the ecology and environment, promoting the sound development of biotechnology, boosting the construction of a community with a shared future for mankind, and achieving the harmonious coexistence of man and nature'. The goal system mirrors the coordination between development and security.

3.3 Principles of the Construction of the Legal System of National Biosafety

Biosafety ranges widely and it is impossible for the Biosecurity Law to emphasize all aspects. Therefore, we should focus on specific aspects and govern bio-risks in classification. At the same time, under the global biological risk background, life technology risk and public health crisis are priorities, which pose more complex risk scenarios and characteristics. In order to achieve the goal of national biosafety legal governance, the national biosafety legal system with Chinese characteristics should follow the basic principles of risk prevention, public participation, classification management, strict responsibility and international cooperation.

4. The Mode and Path of the Construction of Legal System of the National Biosafety

4.1 The Regulatory Object and Scope of the Legal System of National Biosafety

The regulatory object of the national biosafety legal system is biosecurity (which is also called biosecurity), but it is difficult to make a clear distinction between the two expressions in law. In terms of the connotation of biosecurity, it refers to the state of biosafety (description of facts),

measures of biosafety (principles, technology and practice), capabilities of biosafety, and values of biosafety. In the Biosecurity Law, biosafety means that “the state effectively prevents and responds to the threat of dangerous biological agents and related factors, biotechnology can develop steadily and healthily, neither the lives and health of the people nor the ecosystem is relatively in danger or under threat, and there is capability in the biological field to maintain national security and sustainable development.” (Article 2). This defines biosecurity as a national capability (“in the biological field...there is capability to maintain national security and sustainable development”), a status (“biotechnology can develop steadily and healthily, neither the lives and health of the people nor the ecosystem is relatively in danger or under threat”).

In terms of the extension of biosecurity, “biology” includes humans and other creatures and “security” includes not only traditional security issues, such as laboratory security, public health, animal or plant disease prevention and control, environmental and ecological security, the invasion of alien species, entry and exit administration, food and drug management, but also the non-traditional security issues, like modern biotechnology application risks, human genetic resources management, biological terrorism, biological hacker, and biological weapons.

From the perspective of the overall national security outlook, biosecurity extends widely, and superimposes or overlaps with technological security, ecological security, resource security, information security, economic security, social security, military security and other fields. Therefore, considering China's specific legal system and legislative costs, a relatively broad regulatory scope of the legal system of national biosafety has been formed.^[5]

4.2 The Construction Model of the Legal System of National Biosafety

The biosecurity field is broad and the legal system of national biosafety is large and scattered, thus functionalism oriented “Integration+Categorization” regulatory model should be adopted. Construction and function are two sides of the same coin, it is the same with biosecurity legal government. In order that the institution functions better, it is necessary to pay attention to the internal structure of the biosecurity field and legal governance.

The “Integration” path embodies the essential composition and general characteristics of legal system of national biosafety, and highlight the value goals and system functions of legal system of national biosafety. The “Categorization” approach focuses on the specific nature and individual characteristics of different biosecurity fields. For example, concretely systematic measures are taken to integrate biosecurity legal system, which will help legal system work better. The Biosecurity Law embodies ‘Integration’, while other laws and legal rules embody ‘Categorization’

Such regulatory model can focus on the most needed biosecurity governance issues, like the security of human genetic resources, biotechnology risks, and major public health crises.

4.3 Formation of the Legal System of National Biosafety

Given the current legal background, legislative process, and future trends, the legal system of national biosafety with Chinese characteristics will be developed by “three steps” and presented in a general-specific structure.

The first step is to implement basic systems of the Biosecurity Law as soon as possible. General provision of the Biosafety Law outlines the legal system generally, under it different objects should be regulated separately. Based on “the extraction of common factors”, the Biosafety Law stipulates legislative purpose, basic principles, legal responsibilities and other generally applicable rules. The Biosecurity Law covers the prevention and control of major or sudden outbreaks of infectious diseases and epidemics in animals and plants, security of biotechnology research, development, and application, laboratory biosecurity, security of human genetic resources and biological resources, prevention of the invasion of alien species and biodiversity protection, antimicrobial resistance response, biological terrorist attacks prevention and defence of biological weapon threats. The scope of regulation deserves recognition. In order to fill blind spots of current legislations, the subsection of the Biosecurity Law specifically stipulates some urgent major regulatory domain systems. Though antimicrobial resistance issues are mentioned, no specific regulatory provisions are provided.

The second step is to cohere the Biosecurity Law with the Law on Prevention and Treatment of Infectious Diseases, Environmental Protection Law, Wild Animal Conservation Law, Food Safety Law, Pharmaceutical Administration Law, Emergency Response Law, Law on the Entry and Exit Animal and Plant Quarantine, Frontier Health and Quarantine Law and other current laws. These laws have provided institutions related to public health, environmental protection, food and drug security, wild animal conservation, emergency response and others, but they should be revised in time under new biosecurity governance situations to form a healthy, coordinated and orderly connection system.

The third step is to legislate new laws such as Gene Technology Law, Biomedical Technology Law, Law on Administration of Human Genetic Resources and Ecological Damage Compensation Law on the basis of existing administrative regulations and rules when the time is ripe, and competent authorities shall timely supplement, form or perfect the biosecurity governance technology norms (such as Biosecurity Assessment Technical Rule) and ethical principles in various fields to form a strict technical guarantee mechanism.

4.4 The Composition Of institutional Guarantee System of National Biosafety

Under the national biosafety legislation, a scientific and reasonable biosecurity institutional guarantee system has been formed. This institutional guarantee system consists of guarantee mechanism of the capability for national biosafety governance (including but not limited to construction of decision-making and execution system, technological guarantee, financial and material support), mechanism of classified supervision, mechanism of risk monitoring, early warning and emergency response, mechanism of risk management (including but not limited to public engagement, informational communication, educational training and international cooperation), mechanism of recovery and remediation, mechanism of biosecurity defense, mechanism of legal responsibility and others. When it comes to legal liabilities, Articles 1008 and 1009 the Civil Code adopted on May 28, 2020, provide the regulatory basis of clinical experiments, gene editing and embryo testing. While Amendment (XI) to the Criminal Law clarify the criminal liabilities of crimes that harm biosafety, such as prevention and treatment of infectious, human genetic resources, gene editing and clone, protection of wild animal, invasive alien species.

Enforceability and effectiveness of the mentioned institutional guarantee system should be enhanced. It is necessary to establish a reasonable organization and leadership mechanism, clarify relationships among competent authorities in different fields, and set up a complete legal responsibility system to prevent competent authorities from hesitating to perform or shirking their duties.

In this institutional guarantee system, the key is reasonably constructing guarantee mechanism of capability for national biosafety governance (including but not limited to construction of decision-making and execution system, technology guarantee reasonably, financial and material support). China's Biosecurity Law establishes a National Biosecurity Work Coordination Mechanism which is in the charge of the central national security leadership institution. Among them, the "National Biosecurity Expert Committee" is an advisory institution subordinated to the National Biosecurity Work Coordination Mechanism and unable to decide dependently. In order to better reflect the professionalism, efficiency, authority, and effectiveness of biosecurity governance, it is recommended to establish an independent "National Biosecurity Committee" (main members of which are heads of competent authorities and technical experts) under the National Security Committee, making it a decision-making and execution center for biosecurity risk governance. Of course, the National Security Committee should have the final say on major biosecurity issues related to national security, such as against biological terrorism and biological weapons. Under the National Biosecurity Committee, an independent national ethics review institution (composed of competent authorities, technical experts and the public) and a scientific consulting agency (composed of technical experts) are responsible for developing ethical norms and technical standards for biosecurity governance. In order to respond to potential biological terrorism threats, the National Biosecurity Committee should form a national biological defense strategy as early as

possible, and construct the biosecurity defense systems, strengthen biological defense capabilities, and safeguard national biosecurity.

5. Conclusion

In the face of global biological risks, China is systematically arranging mechanism and innovating institutions in biosecurity under the guidance of the overall national security outlook, and building the legal system of national biosafety with Chinese characteristics based on the Biosecurity Law. According to the regulatory model of “Integration + Categorization”, China is implementing basic institutions of the Biosecurity Law, which leads and coordinates other laws and regulations, technical norms, ethical principles, national standards. They constitute the national biosafety legal system and institution guarantee system. In global biosecurity governance, the legal system of national biosafety with Chinese characteristics is born to be a modern and forward-looking model.

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