Biosecurity Law of the People’s Republic of China

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Chapter I — General Provisions

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Article 1 — This Law is enacted for the purpose of safeguarding national security, preventing and responding to biosecurity risks, protecting the life and health of the people, protecting biological resources and the ecological environment, promoting the healthy development of biotechnology, and promoting the building of a community with a shared future for mankind.

Article 2 — For the purposes of this Law, “biosecurity” means the effective prevention and response of the State to threats from dangerous biological factors and related factors, the stable and healthy development of biotechnology, the maintenance of the relative absence of threat and danger to people’s life and health and the ecosystem, and the State’s capacity to ensure security in the biological field and to maintain sustainable development. This Law shall apply to the following activities: (1) prevention and control of major emerging infectious diseases and animal and plant epidemics; (2) research, development, and application of biotechnology; (3) biosafety management of pathogenic microorganism laboratories; (4) security management of human genetic resources and biological resources; (5) prevention of invasion of alien species and protection of biodiversity; (6) response to microbial resistance; (7) prevention of bioterrorism attacks and defense against biological weapons threats; (8) other activities related to biosecurity.

Article 3 — Biosecurity is an important component of national security. The holistic view of national security shall be adhered to, and the principles of people-centeredness, risk prevention, classified management, and coordination and cooperation shall be followed.

Article 4 — The State shall adhere to the leadership of the Communist Party of China over biosecurity work, establish and improve the national biosecurity leadership system, and strengthen the building of the national biosecurity risk prevention and control and governance system to improve the national biosecurity governance capability.

Article 5 — The State shall encourage innovation in biotechnology, strengthen the construction of biosecurity infrastructure and the cultivation of biosecurity talent, support the development of the biosecurity industry, and promote the improvement of biosecurity technology through innovation.

Article 6 — The State shall strengthen international cooperation in the field of biosecurity, fulfill international obligations, and promote global biosecurity governance.

Article 7 — The people’s governments at various levels and their relevant departments shall strengthen the publicity and popularization of biosecurity laws, regulations, and knowledge, guide the public in strengthening biosecurity awareness, and enhance the public’s capacity to prevent and respond to biosecurity risks. News media shall carry out public welfare publicity on biosecurity laws, regulations, and knowledge, and conduct public opinion supervision over illegal biosecurity acts.

Article 8 — No entity or individual shall endanger biosecurity. Any entity or individual shall have the right to report acts endangering biosecurity. The departments that receive reports shall handle them in a timely manner in accordance with the law.

Article 9 — People’s governments at or above the county level and their relevant departments shall commend and reward entities and individuals that have made outstanding contributions to biosecurity work in accordance with State regulations.

Article 10 — The State shall establish a biosecurity risk monitoring and early warning system. The national biosecurity coordination mechanism shall organize the establishment of a national bioseafety risk monitoring and early warning system to improve the capacity of biosecurity risk identification and analysis.

Article 11 — The State shall establish a biosecurity risk investigation and assessment system. The national biosecurity coordination mechanism shall, based on the risk monitoring data and information, organize regular biosecurity risk investigation and assessment.

Article 12 — The State shall establish a bioseafety information sharing system. The national biosecurity coordination mechanism shall organize the establishment of a unified national biosecurity information

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platform.

Article 13 — The State shall establish a biosecurity information release system. Major biosecurity incident information shall be released by the national biosecurity coordination mechanism.

Chapter II — Biosecurity Risk Prevention and Control System

Article 14 — The national biosecurity coordination mechanism shall organize the formulation of a national biosecurity risk prevention and control plan and medium- and long-term objectives. Relevant departments shall, in accordance with the division of functions, organize the implementation.

Article 15 — The State shall establish a biosecurity risk monitoring system. The national biosecurity coordination mechanism shall organize and coordinate departments to strengthen the monitoring of biosecurity risk information and data collection. Relevant departments shall report risk information in accordance with regulations.

Article 16 — The State shall establish a biosecurity risk assessment system. The national biosecurity coordination mechanism shall organize risk assessments, including risk identification, risk analysis, and risk evaluation.

Article 17 — The State shall establish a biosecurity risk early warning system. When a biosecurity risk may occur or has already occurred, relevant departments shall issue early warnings in a timely manner and take corresponding prevention and control measures.

Article 18 — The State shall establish a biosecurity incident emergency response mechanism. After a biosecurity incident occurs, the relevant people's government and its departments shall immediately activate the emergency response plan, take containment measures, and minimize harm.

Article 19 — The State shall establish a biosecurity post-incident recovery mechanism. After the response to a biosecurity incident ends, the relevant people's government shall organize post-incident recovery and reconstruction work in a timely manner.

Chapter III — Prevention and Control of Outbreaks of Infectious Diseases

Article 20 — The State shall establish a joint prevention and control mechanism for the prevention and control of outbreaks of infectious diseases. The competent health department shall be responsible for organizing and coordinating the prevention and control of infectious diseases.

Article 21 — Disease prevention and control institutions, medical institutions, and port health quarantine authorities shall monitor, report, and respond to infectious diseases in accordance with the law. No entity or individual may conceal, delay, or falsely report an epidemic.

Article 22 — Any entity or individual discovering an infectious disease case or suspected case shall promptly report it to the nearby disease prevention and control institution or medical institution.

Article 23 — The State shall establish an early warning system for infectious disease epidemics. The competent health department shall issue early warnings to the public based on the epidemic situation.

Article 24 — The State shall implement a vaccination system. Residents shall receive vaccination in accordance with State regulations. The State shall ensure the quality and supply of vaccines.

Article 25 — Port authorities shall implement health quarantine measures for persons, conveyances, goods, and articles entering or exiting the country to prevent cross-border transmission of infectious diseases.

Article 26 — The State shall establish a system for the emergency production, procurement, and reserve of medicines, medical equipment, and other materials for the prevention and control of infectious diseases.

Chapter IV — Prevention and Control of Major Emerging Infectious Diseases

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Article 27 — The State shall strengthen the monitoring and early warning of major emerging infectious diseases and animal and plant epidemics. Relevant departments shall conduct timely risk assessments and take prevention and control measures.

Article 28 — The State shall establish a system for the investigation and traceability of outbreaks of infectious diseases of unknown origin and major emerging infectious diseases.

Article 29 — The State shall strengthen the management of wild animal epidemic source diseases. The competent departments for wildlife protection and agriculture and rural affairs shall monitor wildlife epidemic diseases.

Article 30 — The State shall strengthen international cooperation in the field of prevention and control of major emerging infectious diseases. Relevant departments may conduct cross-border joint prevention and control as necessary.

Article 31 — Any entity or individual shall not engage in activities that may cause the spread of infectious diseases or animal and plant epidemics. Entities engaged in research on pathogenic microorganisms shall strictly comply with biosecurity management regulations.

Chapter V — Biosafety in Research and Development

Article 32 — The State shall implement classified management of biotechnology research, development, and application activities. Biotechnology research, development, and application activities shall comply with national biosecurity laws, regulations, and ethical standards.

Article 33 — Biotechnology research, development, and application activities shall be subject to risk assessment. For medium- and high-risk biotechnology research, development, and application activities, risk control measures shall be taken.

Article 34 — Entities engaged in biotechnology research, development, and application activities shall establish a biosecurity management system and designate biosecurity management personnel.

Article 35 — Biotechnology research, development, and application activities shall be subject to ethical review. Ethical review committees shall independently conduct reviews in accordance with the law.

Article 36 — The State shall implement a filing or approval system for biotechnology research, development, and application activities that involve biosecurity risks. The specific catalog and measures shall be formulated by the relevant departments under the State Council.

Article 37 — No entity or individual shall engage in biotechnology research, development, and application activities that endanger national security, damage the public interest, violate ethics, or are prohibited by laws and regulations.

Article 38 — The State shall implement a registration and filing system for biotechnology research, development, and application activities conducted in China by foreign organizations or individuals or with the participation of foreign organizations or individuals.

Chapter VI — Biosafety in Laboratories

Article 39 — The State shall implement classified management of pathogenic microorganism laboratories. Laboratories shall be classified into Level I, Level II, Level III, and Level IV according to the level of biosecurity protection. Level III and Level IV laboratories shall be subject to approval for establishment.

Article 40 — Laboratories shall establish a biosecurity management system, designate responsible persons, and strictly manage laboratory activities and the entry and exit of personnel and items.

Article 41 — Laboratory personnel shall receive biosecurity training and shall not engage in laboratory activities without passing the assessment.

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Article 42 — Laboratories shall formulate emergency response plans and conduct regular drills. In the event of a biosafety incident, emergency measures shall be taken promptly.

Article 43 — Pathogenic microorganisms and samples shall be managed in accordance with the law, and their transportation, preservation, and destruction shall comply with State regulations.

Article 44 — Level III and Level IV laboratories shall establish a biosecurity management committee to review and supervise biosecurity matters.

Article 45 — The State shall establish a biosecurity filing and information reporting system for pathogenic microorganism laboratories.

Article 46 — The State shall implement a qualification certification system for laboratory activities involving highly pathogenic microorganisms.

Article 47 — Any entity or individual shall not establish a pathogenic microorganism laboratory or engage in laboratory activities involving pathogenic microorganisms without approval.

Article 48 — The State shall implement a laboratory biosafety incident reporting system. Laboratories shall report biosafety incidents to the relevant departments in accordance with regulations.

Article 49 — The State shall implement a supervision and inspection system for pathogenic microorganism laboratories. Relevant departments shall conduct regular or random inspections of laboratories.

Article 50 — The State shall establish a special management system for animal pathogen laboratories to prevent animal epidemic pathogens from endangering human health and the ecological environment.

Article 51 — The State shall implement special management of laboratories involving the research, development, and application of biotechnology to prevent the misuse or abuse of biotechnology.

Article 52 — The supply, use, storage, and waste disposal of laboratory animals shall comply with national regulations on laboratory animals and biosafety requirements.

Chapter VII — Biosafety of Human Genetic Resources and Biological Resources

Article 53 — The State shall strengthen the protection and supervision of human genetic resources and biological resources, safeguard national biosecurity, and prevent the loss or improper use of resources.

Article 54 — The collection, preservation, utilization, and external provision of human genetic resources within the territory of China shall comply with relevant national regulations on the management of human genetic resources.

Article 55 — The collection, preservation, utilization, and external provision of important biological resources such as animals, plants, and microorganisms shall comply with relevant national regulations on the protection and utilization of biological resources.

Article 56 — Foreign organizations or individuals and organizations established or actually controlled by them within the territory of China that intend to collect, preserve, or utilize human genetic resources within the territory of China shall be subject to the approval of the competent department.

Article 57 — The provision of human genetic resources to foreign organizations or individuals and organizations established or actually controlled by them shall be subject to the approval of the competent department and shall comply with relevant national regulations.

Article 58 — The State shall establish a catalog management system for biological resources. The import and export of biological resources shall be subject to the approval of the competent department.

Article 59 — The State shall take measures to prevent the invasion of alien species, protect biodiversity, and maintain ecological security. Any entity or individual shall not introduce, release, or discard alien species

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without approval.

Article 60 — The State shall strengthen the prevention and response to microbial resistance. Departments such as health, agriculture, and environmental protection shall coordinate and strengthen the supervision of antimicrobial drugs.

Chapter VIII — Prevention and Response to Bioterrorism and Biological Weapons

Article 61 — The State shall prohibit the development, production, acquisition, stockpiling, retention, and use of biological weapons. The State shall prohibit any organization or individual from instigating, assisting, or participating in activities related to biological weapons.

Article 62 — The State shall establish a prevention and response system for bioterrorism and biological weapons threats. Relevant departments of the State Council shall formulate prevention and response plans.

Article 63 — The State shall strengthen the safety and security of biological laboratories and important biological facilities to prevent them from being used for bioterrorism activities.

Article 64 — Relevant departments of the State Council shall organize and coordinate public health institutions, medical institutions, and other relevant entities to conduct monitoring and early warning of bioterrorism incidents.

Article 65 — The State shall fulfill its obligations under the international conventions on the prohibition of biological weapons and shall strengthen international cooperation in the field of biosecurity.

Chapter IX — Biosecurity Capacity Building

Article 66 — The State shall formulate a biosecurity development plan and strengthen the building of biosecurity capacity. People's governments at various levels shall include biosecurity capacity building in their national economic and social development plans.

Article 67 — The State shall strengthen the cultivation of biosecurity talent and support scientific research and innovation in the field of biosecurity. Higher education institutions and research institutions shall strengthen biosecurity discipline development.

Article 68 — The State shall strengthen the building of biosecurity infrastructure, including biosecurity laboratories, monitoring networks, and information platforms.

Article 69 — The State shall encourage and support biosecurity scientific research and technology development, and promote the transformation and application of biosecurity technology achievements.

Article 70 — The State shall establish a biosecurity funding guarantee mechanism to include necessary funds in the government budget.

Article 71 — The State shall strengthen publicity and education on biosecurity, incorporate biosecurity knowledge into the national education system, and enhance the public's biosecurity awareness.

Chapter X — Legal Liability

Article 72 — Where an entity, in violation of the provisions of this Law, engages in biotechnology research, development, and application activities, it shall be ordered to cease the illegal activities, and the illegal income shall be confiscated. A fine shall be imposed in accordance with the law. If the circumstances are serious, the relevant license may be revoked.

Article 73 — Where an entity, in violation of the provisions of this Law, establishes a pathogenic microorganism laboratory without approval or engages in laboratory activities without approval, it shall be ordered to cease the illegal activities and a fine shall be imposed.

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Article 74 — Where laboratory activities cause the leakage, loss, or spread of pathogenic microorganisms, the laboratory shall take immediate control measures and the relevant department shall impose penalties in accordance with the law.

Article 75 — Where an entity, in violation of the provisions of this Law, collects, preserves, utilizes, or provides human genetic resources externally without approval, penalties shall be imposed in accordance with the law.

Article 76 — Where an entity, in violation of the provisions of this Law, introduces, releases, or discards alien species, causing harm, penalties shall be imposed in accordance with the law.

Article 77 — Where a violation of the provisions of this Law constitutes a crime, criminal liability shall be pursued in accordance with the law.

Article 78 — Where a violation causes damage to others, civil liability shall be borne in accordance with the law.

Article 79 — Functionaries of State organs who commit malpractices for personal gain, abuse their powers, or neglect their duties in biosecurity management shall be subject to sanctions in accordance with the law.

Article 80 — Where the violation is committed by an overseas organization or individual, in addition to the penalties stipulated in this Law, measures such as restriction of entry or deportation may be taken in accordance with the law.

Chapter XI — Supplementary Provisions

Article 81 — For the purposes of this Law, the following terms shall have the following meanings: (1) “Biosecurity risk” means the risk arising from dangerous biological factors, including the risk of disease outbreaks, the risk of misuse of biotechnology, the risk of laboratory biosafety incidents, the risk of loss of biological resources, and other risks. (2) “Pathogenic microorganism” means a microorganism that can cause disease in humans, animals, or plants. (3) “Biotechnology” means technology that uses biological organisms or biological processes to manufacture or modify products, improve plants or animals, or develop microorganisms for specific purposes. (4) “Human genetic resources” means genetic materials such as human organs, tissues, and cells that contain information on the human genome, genes, and gene products.

Article 82 — Biosecurity management of activities involving biological agents and toxins in national defense research, production, and testing shall be governed by relevant laws and administrative regulations.

Article 83 — Where biosecurity incidents occur due to force majeure or emergencies, measures may be taken in accordance with the law, and reports shall be made to the relevant departments in a timely manner.

Article 84 — The standing committee of the people’s congress of a province, autonomous region, or municipality directly under the Central Government may, in accordance with this Law, formulate specific measures for biosecurity management within its administrative region.

Article 85 — Biosecurity management activities shall comply with the provisions of this Law. Where other laws or administrative regulations have provisions on biosecurity management, such provisions shall prevail.

Article 86 — The People’s Republic of China shall carry out international exchanges and cooperation in the field of biosecurity in accordance with the law. The State shall conclude or accede to international treaties on biosecurity and undertake corresponding international obligations.

Article 87 — Activities in the Hong Kong Special Administrative Region and the Macao Special Administrative Region relating to biosecurity shall comply with the provisions of this Law, unless otherwise provided for by the basic laws of the special administrative regions.

Article 88 — This Law shall take effect as of April 15, 2021.

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