Biosecurity Law of the PRC

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Chapter I — General Provisions

Article 1 — This Law is enacted for the purposes of safeguarding national security, preventing and responding to biosecurity risks, safeguarding the lives and health of the people, protecting biological resources and the ecological environment, promoting the sound development of biotechnology, promoting the building of a community with a shared future for mankind, and realizing the harmonious coexistence of man and nature.

Article 2 — "Biosecurity" as used in this Law means the effective prevention and response to threats posed by the following factors and related risk factors to the State, by dangerous biological factors to the life and health of the people, and to the ecosystem, and the State's capability in this field: (1) major emerging infectious diseases and animal and plant epidemics; (2) biotechnology research, development and application; (3) biosecurity of pathogenic microorganism laboratories; (4) biosecurity of human genetic resources and biological resources; (5) invasion of alien species and protection of biodiversity; (6) countering microbial resistance; (7) prevention of bioterrorism attacks and biological weapon threats; and (8) other biosecurity-related activities.

Article 3 — Biosecurity is an important component of national security. The holistic approach to national security shall be upheld, the overall leadership of the State over biosecurity work shall be upheld, a biosecurity risk prevention and control system shall be established and improved, and the people's capability for biosecurity governance shall be raised.

Article 4 — The principles of safeguarding the people, preventing risks, exercising categorized management, and coordinating upper and lower-level efforts shall be adhered to in biosecurity work.

Article 5 — The State shall encourage innovation in biotechnology, strengthen the construction of the biosecurity infrastructure and the cultivation of biosecurity professionals, strengthen biological data resources and the sharing and utilization of information, improve the level of biosecurity technology, and support the development of the biosecurity industry.

Article 6 — The State shall strengthen international cooperation in the field of biosecurity, fulfill its obligations under international treaties to which the People's Republic of China is a party or acceded, support participation in exchanges and cooperation on biosecurity science and technology and international rescue of biosecurity incidents, actively participate in the research and formulation of international biosecurity rules, and promote the improvement of global biosecurity governance.

Article 7 — People's governments at all levels and their relevant departments shall strengthen the publicity and popularization of biosecurity laws and regulations and biosecurity knowledge, guide primary-level autonomous organizations of a mass character and social organizations in carrying out publicity activities on biosecurity laws and regulations and biosecurity knowledge, promote relevant scientific research institutions, institutions of higher education, enterprises and public institutions in placing biosecurity education and training as an important part of their work, and strengthen the cultivation of students' and practitioners' awareness of biosecurity. Relevant media shall carry out publicity for the public interest on biosecurity laws and regulations and biosecurity knowledge, conduct public opinion supervision over biosecurity violations, and enhance the awareness of biosecurity throughout society.

Article 8 — All entities and individuals must not endanger biosecurity. All entities and individuals shall have the right to report any act endangering biosecurity; the relevant department receiving such report shall process it in a timely manner in accordance with 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 relevant State provisions.

Chapter II — Biosecurity Risk Prevention and Control System

Article 10 — The central leading body for national security shall be responsible for the research, deployment and command of major biosecurity work, the establishment of a national biosecurity work coordination mechanism, the analysis and assessment of the national biosecurity situation, and the organization, coordination and supervision of the advancement of national biosecurity work.

Article 11 — The national biosecurity work coordination mechanism shall be composed of the competent departments of health, agriculture and rural affairs, science and technology, foreign affairs and other relevant military and civilian departments under the State Council, and shall carry out analysis and research, organize coordination and supervise and advance biosecurity-related work in accordance with the division of duties. The national biosecurity work coordination mechanism shall establish an office to be responsible for the daily work of the coordination mechanism. The member entities of the national biosecurity work coordination mechanism and the relevant departments of the State Council shall be responsible for biosecurity-related work in accordance with the division of duties.

Article 12 — The national biosecurity work coordination mechanism shall establish a national biosecurity expert committee to provide decision-making consultation for biosecurity work such as the research of national biosecurity strategies and the analysis and assessment of biosecurity situations.

Article 13 — Local people's governments at all levels shall be responsible for biosecurity work within their respective administrative regions. The relevant departments of local people's governments at or above the county level shall be responsible for biosecurity-related work in accordance with the division of duties. Primary-level autonomous organizations of a mass character shall assist local people's governments and the relevant departments in carrying out biosecurity risk prevention and control, emergency response and other work. Relevant entities and individuals shall cooperate in carrying out biosecurity risk prevention and control, emergency response and other work.

Article 14 — The State shall establish a biosecurity risk monitoring and early warning system. The national biosecurity work coordination mechanism shall organize the establishment of a national biosecurity risk monitoring and early warning system to improve the capability of biosecurity risk identification, analysis and information monitoring and early warning, and timely issue biosecurity risk early warning information.

Article 15 — The State shall establish a biosecurity risk investigation and assessment system. The national biosecurity work coordination mechanism shall, based on risk monitoring data, information and other relevant materials, periodically organize biosecurity risk investigation and assessment. The relevant departments shall, in accordance with the division of duties, promptly organize biosecurity risk investigation and assessment in their respective fields. Entities that may cause biosecurity harm shall promptly organize biosecurity risk investigation and assessment and take effective biosecurity risk prevention and control measures.

Article 16 — The State shall establish a biosecurity information sharing system. The national biosecurity work coordination mechanism shall organize the establishment of a unified national biosecurity information platform, and the relevant departments shall submit biosecurity data, information and other relevant materials on the platform for sharing.

Article 17 — The State shall establish a biosecurity information publication system. Major biosecurity information such as the overall situation of national biosecurity, early warning information on major biosecurity risks, major biosecurity incidents and their investigation and handling information, and other major biosecurity information shall be published by the member entities of the national biosecurity work coordination mechanism in accordance with the division of duties. No other entity or individual may publish such information. Without authorization, no entity or individual may publish biosecurity information that the

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State has stipulated shall be kept confidential.

Article 18 — The State shall establish a catalog and list system for biosecurity. The State Council and its relevant departments shall, based on biosecurity work needs, formulate, publish and adjust in a timely manner the catalog and list of materials, equipment, technologies, activities, data and information, important biological resources, invasive alien species and other areas of biosecurity, and implement dynamic management over biosecurity risks.

Article 19 — The State shall establish a biosecurity standards system. The standardization administrative department of the State Council and other relevant departments of the State Council shall, in accordance with the division of duties, formulate and timely improve the relevant standards for bioseecurity. The national biosecurity work coordination mechanism shall organize the relevant departments to strengthen the coordination and convergence of standards in different fields, and establish and improve the bioseecurity standards system.

Article 20 — The State shall establish a biosecurity review system. For important biotechnologies, biological products, biological materials, biological data and other factors that affect or may affect national security, a biosecurity review shall be conducted. The specific measures for biosecurity review shall be formulated by the relevant departments of the State Council.

Article 21 — The State shall establish a unified leadership, coordinated and orderly biosecurity incident emergency response system. The relevant departments of the State Council shall organize the formulation of emergency response plans for biosecurity incidents in their respective fields, and strengthen emergency preparedness, personnel training and emergency drills. People's governments at or above the county level and their relevant departments shall formulate and organize the implementation of emergency response plans for biosecurity incidents, strengthen emergency preparedness, personnel training and emergency drills, carry out biosecurity incident emergency response, popularization and prevention, and control the occurrence and spread of biosecurity incidents in accordance with law.

Article 22 — The State shall establish a biosecurity incident investigation and tracing system. After a major biosecurity incident occurs, the national biosecurity work coordination mechanism shall organize investigation and tracing to determine the nature of the incident, conduct a comprehensive assessment of the impacts, and propose handling opinions.

Article 23 — The State shall establish a system for the entry of animals and plants, animal and plant products, and high-risk biological agents for the first time or after resumption. The entry of animals and plants, animal and plant products, and high-risk biological agents that enter the country for the first time or after resumption shall be approved by the relevant departments of the State Council; upon approval, the relevant entities shall file with the relevant departments of the State Council. For animal and plant epidemics and infectious disease risks that may arise from such entry, risk prevention and control measures such as technical specifications and epidemic prevention requirements shall be formulated in a timely manner.

Article 24 — The State shall establish a response system for major biosecurity incidents occurring overseas. Where major biosecurity incidents such as major emerging infectious diseases and animal and plant epidemics occur overseas and spread into or may spread into China, measures such as emergency prevention and control shall be taken in accordance with law, and entry and exit control measures shall be strengthened, with necessary international joint prevention and control measures being adopted when necessary.

Chapter III — Prevention and Control of Major Emerging Infectious Diseases, and Animal and Plant Epidemics

Article 25 — People's governments at or above the county level shall strengthen the construction of the prevention and control capacity for animal and plant epidemics and infectious diseases, establish a

monitoring system for animal and plant epidemics and infectious diseases, and improve the monitoring and early warning capability.

Article 26 — The State shall establish an information reporting and publication system for animal and plant epidemics and infectious diseases. Any entity or individual discovering an infectious disease or an animal or plant epidemic shall promptly report it to a medical institution, relevant professional institution or department. The medical institution, professional institution and relevant department shall promptly report any infectious disease or animal or plant epidemic to the competent department of health, the competent department of agriculture and rural affairs, and the competent department of forestry and grassland respectively, and shall also take necessary prevention and control measures. The media shall timely, accurately and objectively report on animal and plant epidemics and infectious diseases in accordance with law.

Article 27 — The departments of the State Council responsible for health, agriculture and rural affairs, forestry and grassland, customs, ecology and environment shall establish a network for joint monitoring of infectious diseases, animal and plant epidemics, inbound and outbound quarantine, and biosecurity risks, organize cross-sectoral consultations on epidemiological investigation, isolation and quarantine, and animal and plant disease testing and treatment.

Article 28 — Where an animal or plant epidemic occurs, the relevant entity and individual shall immediately take measures such as sealing off, isolation and killing to prevent the spread of the epidemic. People's governments at or above the county level and their relevant departments shall promptly take animal and plant disease prevention and control measures in accordance with law. Major animal and plant epidemics shall be reported to the national biosecurity work coordination mechanism in accordance with law.

Article 29 — The State shall strengthen the biosafety management of laboratory activities involving infectious diseases and animal and plant diseases, and strictly control the deliberate release or use of infectious disease pathogens and animal and plant disease pathogens under experimental conditions. Research and development activities involving the use of highly pathogenic microorganisms and highly toxic animal and plant disease pathogens shall be subject to approval by the relevant departments of the State Council.

Article 30 — The State shall strengthen the construction of joint prevention and control mechanisms for major infectious diseases and animal and plant epidemics inside and outside border areas. Where a major biosecurity incident such as a major emerging infectious disease or animal or plant epidemic occurs overseas, customs shall strengthen port health quarantine and animal and plant quarantine in accordance with law, and take border control measures when necessary.

Chapter IV — Security of Biotechnology Research, Development and Application

Article 31 — The State shall strengthen the security management of biotechnology research, development and application activities, formulate safety management norms for biotechnology research, development and application activities, and prevent biosecurity risks. Entities and individuals engaged in biotechnology research, development and application activities shall strictly comply with the ethical norms of biotechnology research, development and application activities and be responsible for the safety of their research, development and application activities.

Article 32 — The State shall implement categorized management of biotechnology research, development and application activities. Based on the degree of potential harm to public health, industry, agriculture and the ecological environment, biotechnology research, development and application activities shall be categorized as high-risk, medium-risk or low-risk. Biotechnology research, development and application activities shall comply with the relevant national biosecurity management norms and standards. The specific measures for the categorized management of biotechnology research, development and application activities shall be formulated by the relevant departments of the State Council.

Article 33 — High-risk and medium-risk biotechnology research, development and application activities shall be carried out by biotechnology professional personnel who are qualified in accordance with law within the legal persons or other organizations that have met the requirements. High-risk biotechnology research, development and application activities shall be subject to approval. The entity engaged in high-risk or medium-risk biotechnology research, development and application activities shall conduct a risk assessment, formulate a risk prevention and control plan and a biosecurity incident emergency response plan, and implement these plans.

Article 34 — The State shall implement a safety management system for genetically modified organisms. For research, development activities involving the field of genetically modified organisms, the relevant management provisions of the State shall be complied with. Specific safety management measures shall be formulated by the relevant departments of the State Council.

Article 35 — Research, development and application activities related to biological warfare and biological agents for biological warfare are prohibited.

Article 36 — The State shall implement a traceability management system for biotechnology research, development and application activities. Entities engaged in biotechnology research, development and application activities shall in accordance with law establish tracking files for their research, development and application activities.

Article 37 — The State shall implement a biological ethical review system for biotechnology research, development and application activities involving human subjects. Research, development and application activities in biotechnology involving human subjects shall be subject to the management of relevant laws and administrative regulations, and comply with the relevant State provisions on medical and health ethics.

Article 38 — Entities and individuals engaged in biotechnology research, development and application activities shall produce truthful records of the research and development and application processes, and may not engage in fabrication, falsification or tampering. Where biotechnology research, development and application activities involve State secrets, they shall also comply with the relevant State provisions on confidentiality.

Chapter V — Biosecurity of Pathogenic Microorganism Laboratories

Article 39 — The State shall implement categorized management of pathogenic microorganism laboratories. Pathogenic microorganism laboratories shall implement a hierarchical management system. Entities engaged in experimental activities involving pathogenic microorganisms shall strictly comply with the relevant national standards and technical specifications for laboratory biosafety, take safety prevention measures, and prevent laboratory safety incidents.

Article 40 — Pathogenic microorganism laboratories shall be established in accordance with the relevant State provisions on biosafety, and shall pass laboratory biosafety reviews. The establishment and management of pathogenic microorganism laboratories shall comply with the provisions of laws and regulations on the administration of biosafety of pathogenic microorganism laboratories.

Article 41 — The State shall strengthen the management of the transportation of pathogenic microorganisms. The transportation of highly pathogenic microorganisms shall be subject to approval in accordance with law. The entry and exit of pathogenic microorganisms shall comply with the relevant State provisions on border health and quarantine and animal and plant quarantine.

Article 42 — The State shall strengthen the security management of pathogenic microorganism laboratories. Security measures shall be adopted to protect pathogenic microorganism laboratories and ensure the security of pathogenic microorganisms and laboratory samples. The storage and use of highly pathogenic microorganisms shall be subject to approval. Entities engaged in experimental activities involving highly

pathogenic microorganisms shall establish and improve security management systems and adopt security measures to strictly prevent the theft, robbery, leakage and illegal transportation of pathogenic microorganisms.

Chapter VI — Biosecurity of Human Genetic Resources and Biological Resources

Article 43 — The State shall strengthen the protection and supervision of human genetic resources and biological resources, safeguard national security and public interests. The use of China's human genetic resources and biological resources shall comply with the provisions of relevant laws and regulations, be in line with public interest ethics, and must not endanger public health, national security or social public interests.

Article 44 — The State shall implement a licensing and filing system for the collection, preservation, utilization and provision abroad of human genetic resources. The collection, preservation, utilization and provision abroad of China's important human genetic resource pedigree, human genetic resources in designated regions, and the types and quantities of human genetic resources specified by the relevant departments of the State Council shall be subject to examination and approval in accordance with law. Where foreign organizations, individuals and institutions established or actually controlled by them collect or preserve China's human genetic resources within the territory of China, or provide them abroad, they shall obtain approval in accordance with law. The specific measures shall be formulated by the relevant departments of the State Council.

Article 45 — The relevant departments of the State Council and local people's governments at or above the county level and their relevant departments shall strengthen the investigation and protection of biological resources, formulate plans for the protection and utilization of important biological resources, strengthen the management of the entry and exit, acquisition and utilization of biological resources, and strengthen the prevention and response to invasive alien species.

Article 46 — No entity or individual may introduce, release or discard alien species without approval. Entities and individuals that have introduced alien species shall adopt safe and reliable prevention and control measures to prevent them from escaping into the wild or entering the natural environment, thus causing harm to the ecosystem. Where an alien species has been illegally introduced, the relevant departments of the people's government at or above the county level shall, in accordance with the division of duties, order it to be captured or sealed off and destroyed within a time limit.

Chapter VII — Prevention of Bioterrorism and Biological Weapon Threats

Article 47 — The State shall take all necessary measures to prevent bioterrorism and biological weapon threats. The development, production, acquisition, stockpiling, retention and use of biological weapons is prohibited. The State shall strengthen the prevention and response capabilities for bioterrorism attacks and biological weapon threats.

Article 48 — The relevant departments of the State Council and the relevant military organs shall, in accordance with the division of duties, strengthen the investigation, monitoring and prevention of bioterrorism and biological weapon threats. The relevant departments of the State Council shall strengthen the safety regulation and risk monitoring of biological toxins and other biological agents that may be used for bioterrorism and biological weapons.

Article 49 — The State Council and its relevant departments shall, in accordance with the division of duties, formulate emergency response plans for bioterrorism incidents and biological weapon attacks, and strengthen drills. Where a bioterrorism incident or biological weapon attack occurs, the relevant departments shall promptly adopt prevention and control measures such as evacuation and isolation of personnel, and medical treatment.

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Chapter VIII — Biosecurity Capacity Building

Article 50 — The State shall formulate a biosecurity development plan, strengthen biosecurity capacity building, and improve the level of biosecurity science and technology to respond to biosecurity incidents. People's governments at or above the county level shall support the research, development and application of biosecurity science and technology, promote the construction of biosecurity infrastructure, coordinate the establishment and operation of biosecurity facilities, and cultivate and introduce biosecurity professionals of various types and at various levels.

Article 51 — The State shall strengthen the construction of the biosecurity information infrastructure, establish a biosecurity data and information sharing mechanism, and promote the interconnection and efficient use of biosecurity information and data.

Article 52 — The State shall strengthen the construction of biosecurity emergency response capacity. People's governments at or above the county level shall support the construction of emergency response teams and emergency response materials reserve depots for biosecurity incidents, allocate reserve materials in accordance with law, and strengthen the construction of emergency response information and technical support.

Article 53 — The State shall strengthen the construction of biosecurity supervision capacity. The relevant departments of the State Council shall, in accordance with the division of duties, strengthen the construction of biosecurity technical support teams, establish a biosecurity supervision and management information system, and improve the technical means for biosecurity supervision and law enforcement.

Chapter IX — Legal Liability

Article 54 — Where the State, in performing biosecurity work, causes damage to the lawful rights and interests of citizens, legal persons and other organizations, it shall provide compensation in accordance with law.

Article 55 — Where an entity engages in any of the following acts in violation of the provisions of this Law, the relevant department of the people's government at or above the county level shall order it to make rectification and issue a warning; where the act causes adverse consequences, it shall also be ordered to cease the relevant activities: (1) failing to carry out risk investigation and assessment in accordance with the provisions of this Law; (2) failing to formulate and implement a risk prevention and control plan or emergency response plan; (3) failing to establish tracking files for biotechnology research, development and application activities; and (4) other acts in violation of the provisions of this Law.

Article 56 — Where an entity, in violation of the provisions of this Law, engages in high-risk biotechnology research, development and application activities without approval, or fails to comply with biosecurity management norms and standards, the relevant department of the people's government at or above the county level shall order it to cease the relevant activities, and impose a fine of not less than RMB 100,000 yuan and not more than RMB 1,000,000 yuan on the entity, and a fine of not less than RMB 20,000 yuan and not more than RMB 200,000 yuan on the directly responsible person in charge and other directly responsible personnel.

Article 57 — Where an entity engages in biological warfare and the research, development or application activities of biological agents for biological warfare in violation of the provisions of this Law, the relevant department of the State Council shall confiscate the illegal gains, instruments, equipment and raw materials, impose a fine of not less than RMB 1,000,000 yuan and not more than RMB 10,000,000 yuan on the entity, and impose a fine of not less than RMB 100,000 yuan and not more than RMB 1,000,000 yuan on the directly responsible person in charge and other directly responsible personnel, and may revoke the relevant licenses and permits; if a crime is constituted, criminal liability shall be pursued in accordance with law.

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Article 58 — Where an entity, in violation of the provisions of this Law, engages in experimental activities involving highly pathogenic microorganisms without approval, or fails to adopt security measures for pathogenic microorganism laboratories as required by the State, the relevant department of the people's government at or above the county level shall order it to cease the relevant activities and impose penalties in accordance with the provisions of relevant laws and administrative regulations.

Article 59 — Where an entity, in violation of the provisions of this Law, collects, preserves, utilizes or provides abroad human genetic resources without approval, the relevant department of the State Council shall order it to cease the illegal act, confiscate the illegal gains and the illegally collected and preserved human genetic resources, impose a fine of not less than RMB 500,000 yuan and not more than RMB 5,000,000 yuan on the entity, and impose a fine of not less than RMB 100,000 yuan and not more than RMB 500,000 yuan on the directly responsible person in charge and other directly responsible personnel; where the illegal gains exceed RMB 1,000,000 yuan, a fine of not less than 10 times and not more than 20 times the illegal gains shall be imposed.

Article 60 — Where an entity, in violation of the provisions of this Law, introduces alien species without approval, releases or discards alien species without authorization, the relevant department of the people's government at or above the county level shall, in accordance with the division of duties, order it to capture back, retrieve or destroy the alien species within a time limit, and impose a fine of not less than RMB 10,000 yuan and not more than RMB 50,000 yuan on the entity.

Article 61 — Where a staff member of a State organ, in the course of performing biosecurity supervision and administration duties, neglects his or her duties, abuses his or her power, or engages in malpractice for personal gain, disciplinary action shall be taken in accordance with law; if a crime is constituted, criminal liability shall be pursued in accordance with law.

Article 62 — Where a violation of the provisions of this Law causes damage to others, civil liability shall be borne in accordance with law; where a crime is constituted, criminal liability shall be pursued in accordance with law.

Chapter X — Supplementary Provisions

Article 63 — The People's Liberation Army and the Chinese People's Armed Police Force shall carry out biosecurity work in accordance with the provisions of this Law and the relevant military regulations, and the Central Military Commission may formulate specific measures in accordance with this Law.

Article 64 — This Law shall apply to biosecurity-related activities of foreign organizations and individuals within the territory of the People's Republic of China. Where biosecurity-related activities carried out by foreign organizations and individuals cause biosecurity harm to the People's Republic of China, relevant legal liability shall be pursued in accordance with law.

Article 65 — The relevant laws and administrative regulations shall apply to biosecurity-related matters not specifically provided for in this Law.

Article 66 — This Law shall take effect as of April 15, 2021.

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