

Biosafety 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 biosafety risks, protecting the life and health of the people, protecting biological resources and the ecological environment, promoting the sound development of biotechnology, advancing the building of a community with a shared future for mankind, and achieving the harmonious coexistence of humans and nature.

Article 2 — For the purposes of this Law, "biosafety" refers to the condition in which the State effectively prevents and responds to the threats of dangerous biological factors and related factors, biotechnology can develop steadily and healthily, the life and health of the people and the ecosystem are in a state free from danger and threat, and the biosafety field has the capacity to safeguard national security and 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) management of human genetic resources and biological resources; (5) prevention of invasions by alien species and protection of biodiversity; (6) response to microbial resistance; (7) prevention of bioterrorism attacks and biological weapon threats; (8) other activities related to biosafety.

Article 3 — Biosafety is an important component of national security. The overall national security concept shall be upheld, a national biosafety strategy shall be implemented, and a biosafety risk prevention and control regime that is well-coordinated, scientific, rigorous, and highly effective shall be established.

Article 4 — The State shall adhere to a people-centered approach to biosafety, prevent and control biosafety risks in accordance with the law, safeguard the life and health of the people, and protect people's lawful rights and interests.

Article 5 — The State shall encourage innovation in bioscience and technology, strengthen the construction of biosafety infrastructure and the cultivation of bioscience and technology talent, support the development of the bio-industry, and enhance the level of innovation-driven development with the guarantee of biosafety as a premise.

Article 6 — The State shall strengthen international cooperation in the field of biosafety, fulfill obligations under international treaties to which the People's Republic of China is a party or which it has acceded to, support participation in exchanges and cooperation in bioscience and technology and biosafety incident prevention and response, and promote the development and improvement of the international legal system on biosafety.

Article 7 — People's governments at all levels and their relevant departments shall strengthen publicity and education on biosafety laws, regulations, and knowledge, guide grassroots self-governing organizations of a mass character and social organizations in carrying out publicity of biosafety laws, regulations, and knowledge, and promote the enhancement of the public's biosafety awareness.

Article 8 — No entity or individual shall endanger biosafety. All entities and individuals shall have the right to report acts endangering biosafety. The relevant departments that receive such 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 biosafety work in accordance with relevant State regulations.

Chapter II — Biosafety Risk Prevention and Control Regime

Article 10 — The central leading body for national security shall be responsible for decision-making, deliberation, and coordination of national biosafety work, study, formulate, and guide the implementation of the national biosafety strategy and relevant major guidelines and policies, coordinate major issues and important work of national biosafety, and establish a national biosafety work coordination mechanism. Provinces, autonomous regions, and municipalities directly under the Central Government shall establish local biosafety work coordination mechanisms.

Article 11 — The national biosafety work coordination mechanism shall consist of the departments of foreign affairs, science and technology, agriculture and rural affairs, health, emergency management, customs, ecology and environment, education, commerce, forestry and grassland, market regulation, and military organs of the State Council, etc., to analyze and assess the national biosafety situation, and organize, coordinate, and supervise and urge the advancement of national biosafety work.

Article 12 — The State shall establish a biosafety risk monitoring and early warning system. The national biosafety work coordination mechanism shall organize the establishment of a national biosafety risk monitoring and early warning system to improve the ability to identify and analyze biosafety risk information, and timely issue biosafety risk early warning information.

Article 13 — The State shall establish a biosafety risk investigation and assessment system. The national biosafety work coordination mechanism shall, in light of the needs of biosafety work, organize regular biosafety risk investigations and assessments.

Article 14 — The State shall establish a biosafety information sharing system. The national biosafety work coordination mechanism shall organize the establishment of a unified national biosafety information platform, and relevant departments shall submit biosafety data, materials, and other information to the platform.

Article 15 — The State shall establish a biosafety information release system. Major biosafety information such as the overall national biosafety situation, major biosafety incident early warning information, and investigation and handling information of major biosafety incidents shall be released by the national biosafety work coordination mechanism or relevant State Council departments. No entity or individual may fabricate or disseminate false biosafety information.

Article 16 — The State shall establish a biosafety directory and inventory system. The State Council and its relevant departments shall, in accordance with their respective responsibilities, formulate and publish directories or inventories of materials, equipment, technologies, activities, important biological resource data, biological genetic resources, human genetic resources, invasive alien species, etc. related to biosafety, and adjust them dynamically.

Article 17 — The State shall establish a biosafety standards system. The standardization administrative department of the State Council and other relevant departments of the State Council shall, in accordance with their respective responsibilities, formulate and improve standards in the relevant fields of biosafety. The national biosafety work coordination mechanism shall organize relevant departments to strengthen coordination and convergence among standards in different fields.

Article 18 — The State shall establish a biosafety review system. For important biotechnology and products, research institutions, activities, and other matters that affect or may affect national security, biosafety review shall be conducted. Only those that have passed the biosafety review may carry out corresponding activities.

Article 19 — The State shall establish a unified leadership, coordinated, orderly, and efficient national biosafety emergency response system. The relevant departments of the State Council shall organize the formulation of emergency response plans for biosafety incidents in the relevant fields and fields within their respective jurisdictions, and conduct regular drills.

Article 20 — The State shall establish a biosafety incident investigation and tracing system. Where a major emerging infectious disease, animal or plant epidemic, alien species invasion, or other biosafety incident

occurs, the national biosafety work coordination mechanism shall organize investigations and tracing, determine the nature of the incident, and comprehensively assess the impact of the incident.

Article 21 — Where a foreign country or foreign political organization, organization, or individual commits, instigates, or finances others to commit, or where foreign institutions, organizations, or individuals provide support to domestic institutions, organizations, or individuals for the commission of acts endangering the biosafety of the People's Republic of China in violation of the law, necessary countermeasures shall be taken in accordance with the law.

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

Article 22 — The State shall establish a monitoring system for major emerging infectious diseases and animal and plant epidemics, as well as cross-border transmission of epidemics, incorporating them into the national biosafety risk monitoring and early warning system and the national emergency management system. The relevant State Council departments and local people's governments at or above the county level and their relevant departments shall, in accordance with their respective responsibilities, carry out monitoring of major emerging infectious diseases and animal and plant epidemics, as well as cross-border transmission of epidemics.

Article 23 — Where an infectious disease, animal or plant epidemic, or unexplained cluster disease occurs, the relevant entities and individuals shall report it in a timely manner to the relevant professional institutions or departments. Professional institutions and their staff shall promptly report to the health and agriculture and rural affairs departments in accordance with the prescribed procedures.

Article 24 — The State shall establish a joint prevention and control mechanism for major emerging infectious diseases and animal and plant epidemics. Where a major emerging infectious disease or animal or plant epidemic occurs, necessary measures such as isolation, culling, destruction, sanitization, and quarantine shall be taken in a timely manner in accordance with relevant laws and regulations and emergency response plans to prevent the spread of the epidemic.

Article 25 — The State shall strengthen the national border health and quarantine and animal and plant quarantine work to prevent and control the cross-border transmission of major emerging infectious diseases, animal and plant epidemics, and alien species invasions. No entity or individual may evade quarantine in violation of the law.

Chapter IV — Biosafety of Research, Development, and Application of Biotechnology

Article 26 — The State shall strengthen the safety management of research, development, and application of biotechnology, and prohibit the research, development, and application of biotechnology that endangers national security, harms public interests, violates ethical principles, or contravenes laws and administrative regulations. Research, development, and application activities of biotechnology shall comply with ethical norms.

Article 27 — The State Council and its departments of science and technology, health, agriculture and rural affairs, and other relevant departments shall, in accordance with their respective responsibilities, formulate safety management norms for research, development, and application of biotechnology, formulate and publish directories of important biotechnology, dangerous biotechnology, and biotechnology requiring safety management, and implement classified management.

Article 28 — Those engaged in research, development, and application activities of biotechnology shall be responsible for the safety of such activities, conduct risk assessments, and formulate safety management systems and emergency response plans.

Article 29 — Where research on human genes, embryos, or other biological and medical technologies involves ethical issues, ethical review shall be conducted. Biotechnology research and development activities involving the collection, preservation, utilization, and external provision of China's human genetic resources shall comply with relevant State regulations.

Chapter V — Biosafety of Pathogenic Microorganism Laboratories

Article 30 — The State shall implement classified management of pathogenic microorganism laboratories based on their biosafety protection levels. Pathogenic microorganism laboratories shall comply with national biosafety standards and requirements and obtain approval or be filed for record in accordance with the law.

Article 31 — The establishment of pathogenic microorganism laboratories shall be subject to approval or filing for record by the health or agriculture and rural affairs department in accordance with the law. No entity or individual may establish a pathogenic microorganism laboratory or engage in pathogenic microorganism experimental activities without approval or filing for record.

Article 32 — Pathogenic microorganism laboratories shall establish a sound safety management system, strengthen the management of laboratory biosafety, strictly implement relevant national standards and technical specifications, and take biosafety protection measures.

Article 33 — The transportation and storage of pathogenic microorganism strains and samples shall be managed in accordance with the law, and safety measures shall be taken to prevent theft, robbery, loss, leakage, and diffusion.

Chapter VI — Biosafety of Human Genetic Resources and Biological Resources

Article 34 — The State shall strengthen the management and supervision of the collection, preservation, utilization, and external provision of human genetic resources and biological resources to safeguard national security and public interests.

Article 35 — The collection, preservation, utilization, and external provision of China's human genetic resources shall comply with the principles of ethics and shall not endanger public health, national security, or public interests.

Article 36 — Where foreign organizations or individuals, or institutions established or actually controlled by them, acquire or utilize China's human genetic resources within the territory of China, the matter shall be subject to approval by the science and technology department of the State Council and shall comply with the provisions of laws and administrative regulations on the management of human genetic resources.

Article 37 — The State shall strengthen the protection and management of biological resources, prevent the loss and depletion of biological resources, and protect biodiversity. The collection, preservation, utilization, and external provision of China's biological resources shall comply with relevant State regulations.

Chapter VII — Prevention of Bioterrorism and Biological Weapon Threats

Article 38 — The State shall take all necessary measures to prevent bioterrorism and biological weapon threats. The development, production, acquisition, stockpiling, possession, and use of biological weapons are prohibited. It is prohibited to instigate, finance, or assist others in the development, production, acquisition, or use of biological weapons in any way.

Article 39 — The relevant State Council departments shall formulate, revise, and publish directories of organisms, biotoxins, equipment, or technologies that may be used for bioterrorism activities or the manufacture of biological weapons, and strengthen supervision.

Article 40 — The relevant State Council departments shall, in accordance with the law, supervise the organisms, biotoxins, equipment or technologies, and the relevant import and export items in the directories

specified in the preceding Article.

Chapter VIII — Biosafety Capacity Building

Article 41 — The State shall promote the construction of the biosafety discipline and scientific research layout, improve the national biosafety scientific research and technology innovation capacity, and strengthen international cooperation and exchanges in the field of biosafety.

Article 42 — The State shall strengthen the construction of biosafety infrastructure, build platforms for biosafety scientific research and industrial technology, and enhance biosafety support capacity.

Article 43 — The State shall strengthen the cultivation of biosafety talent, establish and improve the biosafety talent training system, and improve the professional competence of biosafety professionals.

Article 44 — The State shall establish and improve the biosafety funding guarantee mechanism, and include the funds required for biosafety capacity building in the government budget to guarantee the funding needs for biosafety work.

Chapter IX — Legal Liability

Article 45 — Where, in violation of the provisions of this Law, an entity commits any of the following acts, the relevant competent department shall order it to cease the illegal act, confiscate the illegal gains and the items illegally produced, preserved, used, or transported, and impose a fine: (1) engaging in activities such as the research, development, and application of biotechnology without conducting risk assessment or taking risk prevention and control measures; (2) engaging in pathogenic microorganism experimental activities without approval or filing for record; (3) illegally collecting, preserving, utilizing, or externally providing human genetic resources or biological resources. Where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Article 46 — Where a relevant department or its staff member fails to perform biosafety supervision and administration duties in accordance with the law, abuses power, neglects duties, or engages in malpractice for personal gain, sanctions shall be imposed in accordance with the law on the directly responsible person in charge and other directly responsible persons.

Article 47 — Where an entity or individual fabricates or disseminates false biosafety information, which constitutes a violation of public security administration, public security administration penalties shall be imposed in accordance with the law. Where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Chapter X — Supplementary Provisions

Article 48 — Where laws or administrative regulations provide otherwise with respect to biosafety management in specific fields, such provisions shall prevail.

Article 49 — Biosafety management activities related to military systems shall be separately prescribed by the Central Military Commission in accordance with the principles of this Law.

Article 50 — This Law shall take effect as of April 15, 2021.

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