

## **Biosecurity Law of the P.R.C.**

### Chapter I: General Provisions

**Article 1:** This law is formulated so as to maintain national security, prevent and respond to biosecurity risks, safeguards people's lives and health, protect biological resources and the ecological environment, promote the healthy development of biotechnology, promote the construction of a community with a shared future for mankind, and bring about the harmonious coexistence of man and nature,

**Article 2:** The term "biological security" [also biosecurity] as used in this law refers to the nation effectively preventing and responding to the threat of dangerous biological factors and related factors, biotechnology developing steadily and healthily, people's lives and health and ecosystems being in a state of relatively no danger and threats, and the biological field having the capacity to preserve National security and sustainable development.

This law applies to engagement in any of the following activities:

- (1) the prevention and control of major emergent infectious diseases, and outbreaks in animals and plants;
- (2) Security in biotechnology research, development, and applications;
- (3) Biological security management in pathogenic microbiology laboratories;
- (4) the management of security in human genetic resources and biological resources;
- (5) preventing encroachment by foreign species and the preservation of biodiversity;
- (6) responding to microbial drug resistance;
- (7) preventing bioterrorist attacks and defending against the threat of biological weapons;
- (8) other activities related to biological security.

**Article 3:** Biological security is an important component of national security. Preservation of biological security shall implement the overall national security perspective, plan overall development and security, and adhere to the principals of being people-centered, risk prevention, categorical management, coordination and cooperation.

**Article 4:** Uphold the leadership of the Chinese Communist Party over the nation's biological security efforts by establishing and completing a national leadership system for biological security, strengthening the establishment of a system for the prevention, control and government response to biosecurity threats; to increase the nation's ability govern biological security.

**Article 5:** The state encourages innovation in biotechnology, strengthens the construction of biological security infrastructure and biotechnology personnel, supports the development of bioindustries, promotes increases in the level of biotechnology through innovation, and enhances the ability to safeguard biological security.

**Article 6:** The state is to strengthen international cooperation in the biological security sector by performing obligations provided for in international treaties with the P.R.C. has concluded or participates in, supporting participation in exchanges and cooperation on biological science and technology and in international aid for biological security incidents, and actively participating in

research and drafting of international biological security rules, to promote improvements of global biological security governance.

**Article 7:** All levels of people's government and their relevant departments shall strengthen efforts to publicize and spread information on biological security laws and regulations, and biosecurity, leading the basic-level mass autonomous organizations and social organizations in carrying out publicity on biological security laws and regulations, and on biosecurity, to increase the entire society's awareness of biosecurity.

Related scientific and research institutes or schools and medical establishments, as well as enterprises, and public institutions, shall include biological security laws and regulations and biosecurity information in their educational or training curricula to strengthen the cultivation of students' and practitioners' awareness of biosecurity and ethics.

The news media shall carry out public interest publicity on biological security laws and regulations, and on biosecurity, to carry out public opinion oversight on conduct in violation of biological security laws, and increase public awareness of social responsibility for preserving biological security.

**Article 8:** Biological security must not be threatened by any units or individuals.

All Units and individuals have the right to report conduct threatening biosecurity, and departments receiving reports shall promptly address them in accordance with law.

**Article 9:** People's governments at the county level or above and their relevant departments are to give commendations and awards in accordance with state provisions to units and individuals that make outstanding contributions to biological security efforts.

## Chapter II: Biosecurity Risk Prevention and Control Systems

**Article 10:** The Central Leading Group on National Security is responsible for major decision-making, deliberations, and coordination of national biological security efforts; for researching, drafting, and guiding the implementation of the national biosecurity strategy and major, related directives and policies; planning and coordinating major national biosecurity matters and work; and for establishing a National Coordination Mechanism for Biosecurity Work.

Provinces, autonomous regions, and municipalities directly under the Central Government are to establish mechanisms to coordinate efforts on biological security, organizing, coordinating, urging, and promoting work related to biological security within their administrative regions.

**Article 11:** The National Coordination Mechanism for Biosecurity Work is to consist of the State Council's departments in charge of health, rural affairs, science and technology, and foreign affairs, and organs responsible for military affairs; and is to analyze and assess trends in biosecurity, and is to organize, coordinate, and prompt advancements in the nation's biological security work. The National Coordination Mechanism for Biosecurity Work is to set up an office responsible for coordinating routine work.

The member units of the National Coordination Mechanism for Biosecurity Work and other relevant departments of the State Council are responsible for work related to biological security based on their duties and division of labor.

**Article 12:** The National Coordination Mechanism for Biosecurity Work is to establish an experts committee to provide consultation on decision making for the research, policy-drafting, and implementation of the national biological security strategy.

The relevant departments of the State Council are to organize and establish expert biological security technical consultative committees for related sectors and industries to provide consultation, assessment, debate, and technical support for biological security work.

**Article 13:** Local people's governments of all levels are responsible for biological security work in that administrative region.

The relevant departments of local people's governments at the county level or above are responsible for relevant biological security work based on their duties and division of labor.

Basic-level mass autonomous organizations shall coordinate local people's governments and their relevant departments to complete efforts such as on biological security risk prevention and control, emergency response, public and education.

Relevant units and individuals shall cooperate in efforts such as biological security risk prevention and emergency response.

**Article 14:** The state is to establish a biosecurity risk monitoring and early warning system. The National Coordination Mechanism for Biosecurity Work is to organize and establish a national biosecurity risk monitoring and early warning system to increase capacity for recognizing and analyzing biological security risks.

**Article 15:** The state is to establish a biological security risk investigation and assessment system. Based on information such as risk monitoring data and materials, the National Coordination Mechanism for Biosecurity Work shall periodically organize and carry out biosecurity risk investigations and assessments.

In any of the following circumstances, relevant departments shall promptly carry out biological security risk investigation and assessment, and employ the necessary measures for risk prevention and control in accordance with law:

- (1) A potential biosecurity threat is discovered through risk monitoring or receiving a report;
- (2) in order to determine the key sectors or key projects for oversight and management, and formulate or adjust catalogs or lists related to biological security;
- (3) Dangerous biological security incidents such as the occurrence of outbreaks of major new infectious diseases and plant or animal epidemics.
- (4) Other circumstances that require investigation and assessment.

**Article 16:** The State is to establish systems for sharing information on biological security. The National Coordination Mechanism for Biosecurity Work is to organize the construction of a uniform national biosecurity information platform, and relevant departments shall aggregate information such as biosecurity data, materials, and so forth onto the national biosecurity information platform, to bring about information sharing.

**Article 17:** The State is to establish systems for publishing information on biological security. Major biological security information such as the nation's overall biosecurity situation, alerts on major biosecurity risks, and information on major biosecurity incidents and their investigation and handling, is to be published by the member units of the National Coordination Mechanism for Biosecurity Work based on their duties and division of labor; and other biological security information is to be published by local people's governments and their relevant departments based on their duties and division of labor.

Fake biosecurity information must not be fabricated or disseminated by any units or individuals.

**Article 18:** The state is to establish a biological security catalog and list system. As needed for biosecurity efforts, the State Council and its relevant departments are to draft and publish catalogs and lists of materials, equipment, technology, activities, data on important biological resources, contagious diseases, animal and plant diseases, invasive foreign species, etc. that are related to biological security, and dynamically adjust them.

**Article 19:** The state is to establish a system of biological security standards. Based on their duties and division of labor, the State Council departments in charge of standardization and other relevant State Council departments are to draft and improve relevant standards in the biological security sector.

The National Coordination Mechanism for Biosecurity Work is to organize relevant departments in strengthening the coordination and linkage between biosecurity standards in different sectors, establishing and improving the biosecurity standards system.

**Article 20:** The State is to establish a biosecurity review system. For major incidents and activities in the biological field that affect or might affect national security, the relevant departments of the State Council are to conduct a biological security review to effectively prevent and resolve biosecurity risks.

**Article 21:** The State is to establish a bio-security emergency response system with uniform leadership, coordinated linkages, that is orderly and highly effective.

The relevant departments of the State Council shall organize and draft emergency response plans for biosecurity incidents in relevant sectors and industries, carrying out emergency drills, emergency handling, emergency rescue, and post-incident recovery efforts based on the emergency response plans and uniform deployments.

Local people's governments at the county level or above and their relevant departments shall draft, and also organize, guide, and urge related enterprises and public institutions to draft, emergency response plans for biosecurity incidents and strengthening emergency preparedness, personnel training, and emergency drills, and carry out efforts on biosecurity incident emergency handling, emergency rescue, and post-incident recovery.

The Chinese People's Liberation Army and Chinese People's armed police forces are to lawfully participate in emergency handling and rescue efforts for biosecurity incidents as ordered by the central military commission.

**Article 22:** The state is to establish a biosecurity incident investigation and tracing system. In the event of major emergent infectious diseases, animal and plant diseases, or unexplained biosecurity incidents, the National Coordination Mechanism for Biosecurity Work shall organize investigations and tracing, determine the nature of the incident, comprehensively evaluate the impact of the incident, and provide opinions and suggestions.

**Article 23:** The State is to establish a national entry approval system for animals and plants, animal and plant products, and high-risk biological factors that are entering the country for the first time.

Personnel, vehicles, containers, goods, articles, packaging materials, crossing the borders, and water discharged from ships in international navigation, shall comply with our nation's biosecurity management requirements.

Where customs discovers biological security risks for border crossings or transit, they shall handle them in accordance with law. Personnel, vehicles, goods, articles, and so forth that have been assessed as high biological security risks shall enter the country through designated ports of entry and employ strict risk prevention and control measures.

**Article 24:** The state is to establish a system for responding to major overseas biosecurity incidents. Where major biosecurity incidents occur overseas, customs is to lawfully employ emergency biosecurity prevention and control measures, strengthen document verification, increase the rate of inspections, and temporarily suspend relevant persons, transport, goods, and items from entering. When necessary, with the consent of the State Council, measures such as temporary closure of relevant ports and closing relevant borders may be adopted.

**Article 25:** The relevant departments of people's governments at the county level or above shall lawfully carry out efforts on biological security oversight and inspections, and the units and individuals being inspected shall cooperate by truthfully explaining circumstances and providing materials, and must not refuse or obstruct.

Oversight and inspection work that involves a higher level of specialized technology or higher difficulty of enforcement operation, shall have biological security technical professionals participate.

**Article 26:** The relevant departments of people's governments at the county level or above are to carry out biological security oversight inspections and may lawfully employ the following measures:

- (1) Enter the units or locations being inspected, or venues where it is suspected that unlawful biosecurity conduct is being conducted, to carry out on-site monitoring, exploration, inspection or verification;
- (2) Learn about circumstances from relevant units and individuals;
- (3) Access or reproduce relevant documents, materials, files, records, credentials, etc.;
- (4) Inspect venues and facilities where there is suspected unlawful biosecurity conduct;
- (5) Seize tools, equipment, and items related to suspected unlawful biosecurity conduct;
- (6) Other measures provided by laws and administrative regulations.

Information on violations of biosecurity law by relevant units and individuals shall be included in the national credit information sharing platform in accordance with law.

Chapter III: Prevention and Control of Major Emergent Infectious Diseases, and Diseases in Animals and Plants

**Article 27:** The State Council departments in charge of health, rural affairs, forestry and grasslands, customs, and the ecological environment shall establish a network for monitoring emergent infectious diseases and plant and animal diseases, border crossing quarantine, and biotechnology environmental security, organizing the arrangement and construction of monitoring stations, establishing and improving systems for reporting monitoring information, carrying out active monitoring and pathogen testing, and uniformly entering this into the national biological security risk monitoring system.

**Article 28:** Establishments for the prevention of diseases, establishments for the prevention and control of animal and plant diseases, and establishments for the prevention of plant pests (hereinafter called 'professional bodies) shall actively monitor infectious diseases, animal and plant

diseases, and illnesses of unknown cause within the scope of monitoring; and shall collect, analyze, and report monitoring information to predict new emergence of infectious diseases, animal and plant diseases, and contagion trends.

The relevant departments of the State Council, local people's governments at the county level or above, and their relevant departments shall promptly publish warnings based on predictions and the scope of their authority, and employ corresponding measures for prevention and control.

**Article 29:** Where any unit or individual discovers infectious diseases or plant and animal diseases, they shall promptly report it to the medical establishments and relevant professional bodies or departments.

Where medical establishments, professional bodies, and their staffs discover infectious diseases, plant and animal diseases, or illnesses of unknown causes, they shall promptly report them and employ protective measures.

Where a report shall be made in accordance with law, units and individuals must not conceal, falsify, delay, or have omissions in the reporting, must not suggest that others conceal, falsify, or delay reports, and must not obstruct reporting by others.

**Article 30:** The state is to establish a joint prevention and control mechanism for major emergent infectious diseases and plant and animal diseases.

Prevention and control measures shall be promptly employed in the event of major emergent infectious diseases or plant and animal diseases in accordance with relevant laws, regulations and emergency response plans, and the State Council departments of health, agriculture and rural affairs, and forestry and grasslands shall immediately organize the epidemic committee to evaluate, report the outcome of their evaluations to the Central Government National Security Leadership Body and State Council, and notify the National Coordination Mechanism for Biosecurity Work and its member units and the other relevant departments of the State Council.

In the event of major emergent infectious diseases or plant and animal diseases, all levels of local people's government are to uniformly perform epidemic prevention and control duties in their administrative region, strengthening organizational leadership, carrying out group prevention and control, medical assistance, and mobilizing and encouraging social forces to lawfully and orderly participate in epidemic prevention and control efforts.

**Article 31:** The State is to strengthen capacity for the prevention and control of infectious diseases and animal and plant diseases at borders and ports, establishing a collaborative international network for infectious diseases and animal and plant diseases to discover and control major emergent infectious diseases and plant and animal diseases as early as possible.

**Article 32:** The state is to protect wildlife by strengthening the prevention of animal diseases and preventing the transmission of animal-borne illnesses.

**Article 33:** The state is to strengthen management of the use of antimicrobial drugs such as antibiotics and their residues and support basic research and scientific and technological research in response to microbial resistance.

The health authorities of the people's governments at the county level or above shall strengthen the guidance and oversight of the rational use of medicines by medical establishments, and employ measures to prevent the irrational use of antimicrobial drugs. The departments for agricultural and rural affairs and for forestry and grassland administration of people's governments at the county

level or above shall strengthen guidance and oversight of the rational use of medicines in agricultural production, and take measures to prevent the irrational use of antimicrobial drugs, and reduce the residues in agricultural production environments.

Based on their duties and division of labor, the State Council regulatory departments such as for health, agriculture and rural affairs, forestry and grasslands, and ecology and the environment, as well as the Drug Administration shall assess the harm from anti-microbial drug residues to human health and the environment, and establish indexes and appraisal systems for anti-microbial drug contamination.

#### Chapter 4: Security in Biotechnology Research, Development and Applications

**Article 34:** The state is to strengthen security management for biotechnology research, development, and application activities, prohibiting the engagement in technological research, development, and application activities that endanger public health, harm biological resources, or undermine ecosystems and biological diversity.

Engagement in research, development, and application of biotechnologies shall comply with ethical principles.

**Article 35:** Units engaged in the research, development, and application of biotechnologies shall be responsible for the safety of those activities in that unit, shall employ measures to prevent and control biosecurity risks, and shall formulate work mechanisms for biosecurity training, follow-up inspections, periodic reporting, and so forth, to strengthen management in the course of these activities.

**Article 36:** The state is to conduct categorical management for biotechnology research and development activities. Based on the level of threat caused to public health, industry, and agriculture, and the ecological environment, biotechnology research and development activities are to be divided into three levels: high-risk, medium-risk, and low-risk.

Based on their duties and division of labor, the State Council departments in charge of science and technology, health, agriculture and rural affairs, together with other relevant departments of the State Council, are to draft the standards for risk categories and lists for biotechnology research and development activities.

**Article 37:** Those engaged in biotechnology research and development activities shall comply with state specifications on safety management in biotechnology research and development.

Those engaged in biotechnology research and development activities shall conduct risk categorization assessments, pay close attention to changes in the risks, and promptly employ corresponding measures.

**Article 38:** Those engaged in high-risk and medium-risk biotechnology research and development activities shall be lawfully established and organized as legal persons in our country, shall lawfully obtain approvals, and carry out filings.

Those engaged in high-risk and medium-risk biotechnology research and development activities shall conduct risk assessments, draft risk prevention and control plans, and emergency response plan for biosecurity incidents, to reduce the risk of carrying out the research and development activities.

**Article 39:** The state is to implement traceable management of important equipment and special biological factors related to biological security. The purchase or introduction of important

equipment and special biological factors included in the control list shall be registered to ensure traceability and reported for filing to the relevant departments of the State Council.

Individuals must not purchase or possess important equipment and special biological factors included in the control list.

**Article 40:** Engagement in clinical research on new medical technologies shall go through an ethics review and be conducted in medical establishments with the corresponding capacities; clinical research operations on humans shall be conducted by professional health technicians that meet the relevant requirements.

**Article 41:** The relevant departments of the State Council are to conduct follow-up assessments of biotechnology applications and activities, and where discovering biosecurity risks shall promptly employ effective remedial and control measures.

#### Chapter V: Biological Security in Pathogenic Microbiology Laboratories

**Article 42:** The state is to strengthen biosecurity management of pathogenic microbiology labs and draft uniform standards for laboratory biological security. Pathogenic microbiology laboratories shall meet the national standards and requirements on biological security.

Engagement in experiments of pathogenic microbes shall strictly follow relevant national standards, laboratory technical regulations, and operational procedures, and shall employ safety and prevention measures.

**Article 43:** Categorical management is to be implemented for pathogenic microbes, based on the contagiousness of the pathogenic microbes and the extent of harm they do to infected people and animals as individuals or populations.

Those engaged in the collection, storage, or transport of highly pathogenic microbes or suspected highly pathogenic microbes shall have corresponding capacity meeting biological security management specifications. The specific measures are to be formulated by State Council departments for health and rural affairs.

**Article 44:** Approvals shall be obtained or filings completed in accordance with law, for setting up pathogenic microbiology laboratories.

Individuals must not set up pathogenic microbiology laboratories or engage in pathogenic microbiology laboratory activities.

**Article 45:** Hierarchic management is to be carried out for pathogenic microbiology laboratories, bases on the pathogenic microbiology laboratories' biological security protection levels.

Engagement in experimental activities on pathogenic microorganisms shall be carried out in laboratories of corresponding levels. Low-level pathogenic microorganism laboratories must not engage in pathogenic microbiology experimental activities that must be carried out in high-level pathogenic microorganism laboratories as provided by the national pathogenic microorganism catalog.

**Article 46:** High-level laboratories engaging in laboratory activities with highly pathogenic, or suspected highly pathogenic, microbes. shall be approved by the department of health or rural affairs of a provincial-level people's governments, and report on the experimental activities to the approving department.

Experimental activities with pathogenic microbes that have not yet been discovered in our country or that have been announced as eradicated must not be conducted without approvals.

**Article 47:** Pathogenic microbiology laboratories shall employ measures to strengthen the management of experimental animals and prevent their escape, making it so that experimental animals can be traced; and follow state provisions to dispose of experimental animals after use in a manner that renders them harmless and that allows for tracing of experimental animals. It is forbidden to introduce animals used in experimentation into the marketplace.

Pathogenic microbiology laboratories shall strengthen the management of waste from experimental activities, lawfully disposing of waste fluids, gases, and other wastes and employing measures to prevent contamination.

**Article 48:** The units setting up pathogenic microbiology laboratories are responsible for managing the laboratories' biological security by formulating scientific and strict management systems, periodically conducting reviews of the implementation of related biosecurity rules, and reviewing and updating the laboratories' facilities, equipment, and materials, to ensure they meet state standards.

The legal representative and responsible person for units setting up pathogenic microbiology laboratories have responsibility for biological security in the laboratory.

**Article 49:** The units setting up pathogenic microbiology laboratories shall establish and improve security and defense systems by employing measures to safeguard the security of the laboratory and its pathogenic microbes.

The state is to strengthen the security and defense of higher-level pathogenic microbiology laboratories. Higher-level pathogenic microbiology laboratories shall accept oversight and guidance from the public security organs and other departments on laboratory security and defense work, to strictly prevent leaks, loss, and theft or robbery of highly pathogenic microbes.

The state is to establish systems for personnel review at higher-level pathogenic microbiology laboratories. Entry of personnel into higher-level pathogenic microbiology laboratories shall be approved by the person responsible for the laboratory. Where it might impact laboratory biosecurity, it should be approved; and those that are approved to enter shall employ security protection measures.

**Article 50:** The units setting up pathogenic microbiology laboratories shall draft emergency response plans for biological security incidents, and periodically organize personnel in carrying out training and emergency response drills. Where biological security risks such as leaks, loss, and theft or robbery of highly pathogenic microbes occur, control measures shall be promptly employed in accordance with the emergency response plan and reported in accordance with state provisions.

**Article 51:** The provincial-level people's governments where pathogenic microbiology laboratories are located, and their departments for health, shall strengthen allocation of infectious disease resources for the laboratories' regions, to increase the ability to treat infectious diseases.

**Article 52:** Enterprises are to conduct biosecurity management of production workshops involved with operations on pathogenic microbiology in accordance with provisions related to pathogenic microbiology laboratories and other biosecurity management specifications.

The construction and management of biosecurity laboratories involved with biotoxins, plant pests, and other biological elements are to be implemented with reference to the provisions on pathogenic microbiology laboratories.

#### Chapter VI: Security of Human Genetic Resources and Biological Resources

**Article 53:** The state is to strengthen the management and oversight of the collection, storage, use, and external provision of our nation's human genetic resources to ensure the security of human genetic resources and other biological resources.

The state enjoys sovereignty over our country's human genetic resources and biological resources.

**Article 54:** The state is to develop surveys of human genetic resources and biological resources.

The State Council's administrative departments for science and technology are responsible for organizing surveys of our nation's human genetic resources, and for formulating measures for implementing the human genetic resources reporting and registration system for important gene families and specified regions.

Based on their duties and division of labor, the State Council departments in charge of science and technology, natural resources, the environment, health, rural affairs, forests and plains, and Chinese medicine are to organize and carry out surveys of biological resources and draft measures for declarations and registration of important biological resources.

**Article 55:** The collection, preservation, use, or external provision of our nation's human genetic resources shall comply with ethical principles, and must not endanger public health, national security, or the public societal interest.

**Article 56:** Engagement in the following activities shall be upon approval from the State Council regulatory departments for science and technology:

- (1) Those collecting of our nation's important gene families or human genetic resources from specified regions, and collecting types and volumes of human genetic resources provided for by the State Council regulatory departments for science and technology;
- (2) Preservation of our nation's human genetic resources;
- (3) Using our nation's human genetic resources to carry out international research collaboration;
- (4) transporting, mailing, or carrying our nation's human genetic resources out of the mainland.

The provisions of the preceding paragraph do not include the collection and storage of human genetic resources for the purposes of clinical diagnosis and treatment, blood collection and supply services, the investigation of violations and crimes, testing for stimulants, funerals, or other such activities.

Approvals are not required for the use of our nation's human genetic resources by clinical experimentation institutions to carry out of collaborative international clinical experiments, so as to obtain approvals for obtaining permits for the sale of drugs and medical instruments in our nation where it does not involve sending human genetic resources overseas; but before the clinical experiment is carried out, the types and amounts of human resources to be used, as well as their usages, shall be sent for filing to the State Council departments for science and technology.

Foreign [non-mainland] organizations and individuals, as well as institutions they establish or are the actual controllers of, must not collect or preserve human genetic resources within the territory of our nation, and must not provide out nations' human genetic resources outside the territory.

**Article 57:** Where human genetic resources are transferred to foreign [non-mainland] organizations, individuals or bodies that they have established or are the actual controllers of, it shall be reported in advance to the State Council departments for science and technology and a backup copy of the information is to be submitted.

**Article 58:** The collection, storage, use, or transport abroad of species that are rare, endangered, or special to China, as well as specimens, organs, tissues, cells, genes or other genetic resources that might be used for regeneration or reproduction, shall be in compliance with relevant laws and regulations.

Approvals shall be lawfully obtained for the acquisition or use of our nation's biological resources by foreign organizations and individuals and bodies that they have established or control in fact.

**Article 59:** Approvals shall be acquired in accordance with law for the use of our nation's biological resources to carry out international scientific research collaboration.

The use of our nation's human genetic resources or biological resources to carry out international scientific research collaboration shall ensure that the Chinese-side units and their researchers participate substantively in the entire course of research, and lawfully share in the relevant interests.

**Article 60:** The state is to strengthen protection and responses to invasion by foreign species to protect biological diversity. The State Council department for agriculture and rural affairs together with other relevant departments of the State Council is to draft a catalog of foreign invasive species and management measures.

Based on their duties and division of labor, the relevant departments of the State Council are to strengthen investigations, monitoring, warnings, control, assessment, elimination, environmental restoration, and other such efforts on the foreign invasive species.

Units and individuals must not introduce, release, or discard foreign species without approval.

#### Chapter VII: Prevention of Bioterrorism and the Threat of Biological Weapons

**Article 61:** The state is to employ all necessary measures to prevent biological terrorism and the threat of biological weapons.

It is prohibited to develop, create, or use other methods to obtain, store, possess, or use biological weapons.

It is prohibited to incite, fund, or assist others in developing, creating, or otherwise obtaining biological weapons.

**Article 62:** The relevant departments of the State Council are to draft, revise, and publish a list of organisms, biotoxins, equipment or technologies that can be used for bioterrorist activities or production of biological weapons, and strengthen regulation to prevent their use in the creation of biological weapons or for terrorist goals.

**Article 63:** Based on their duties and division of labor, the relevant departments of the State Council and related military organs are to strengthen the monitoring and investigation of activities such as cross-the border, importing or exporting, obtaining, creating, transferring or placement of

organisms, biotoxins, equipment or technologies that can be used for bioterrorist activities or production of biological weapons, and are to take all necessary preventative and disposal measures.

**Article 64:** After bioterrorist incursions or attacks by biological weapons, the relevant departments of the State Council, provincial-level governments, and their relevant departments are responsible for rescue and placement of persons, environmental disinfection, ecological restoration, security monitoring, and restoring social order.

The relevant departments of the State Council, provincial-level people's governments and their relevant departments, shall effectively guide public opinion by scientifically and accurately reporting on bioterrorist attacks and incidents of attacks by biological weapons, promptly reporting information such as on evacuation, transfer, and emergency shelter, and carrying out emergency response and longterm environmental and health monitoring for areas and persons that were contaminated.

**Article 65:** The state is to organize and carry out investigations into the consequences and latent impact of biological weapons behind from wars in our country.

The state is to organize the construction of facilities for placement and disposal of biological weapons left behind from wars in our country, to ensure that such weapons are safely disposed of.

#### Chapter VIII: Building Biosecurity Capacity

**Article 66:** The state is to draft plans for the development of biological security affairs by strengthening biosecurity capacity, increasing the capacity for responding to biosecurity incidents, and increasing the level of response.

People's governments at the county level or above shall support the development of biological security affairs in accordance with the scope of their authority, and include support for the development of the following biosecurity affairs into government budgets:

- (1) Construction and use of a monitoring network;
- (2) Reserves of emergency response and prevention and control materials;
- (3) Construction and utilization of critical infrastructure;
- (4) Research and development of critical infrastructure technology and products;
- (5) development of surveys and storage of human genetic resources and biological resources;
- (6) Other important biological security affairs as provided for by laws and regulations.

**Article 67:** The state is to employ measures to support technical research into biological security, strengthening research into prevention and control of biological security risks, bringing together advantageous forces and resources to establish multi-discipline, multi-departmental mechanisms for joint research that are cooperative and innovative, promoting the inversion and application of scientific and technical payoffs in core critical biosecurity technologies and major defensive products to increase the capacity of technological safeguards for biosecurity.

**Article 68:** The state is to make overall plans for the construction of national biosecurity infrastructure. According to their duties and division of labor, the relevant departments of the State Council are to accelerate the establishment of a national strategic resource platform for biosecurity for areas such as biological information, preservation of human genetic resources, preservation of

bacteria (virus) species, preservation of animal and plant genetic resources preservation, and high-level pathogenic microorganism laboratories, and establish shared usage mechanisms, to provide strategic guarantee and support for technological innovation in biological security.

**Article 69:** Based on their duties and division of labor, the relevant departments of the State Council are to strengthen the cultivation of talent in basic biological research and specialized technical research in the biological areas, to promote the establishment of foundational science and scientific research.

Practitioners in important positions in the state's critical biosecurity infrastructure shall possess the required credentials, the relevant information shall be filed with the relevant departments of the State Council, and they are to accept relevant training for the post

**Article 70:** The state is to strengthen reserves of biosecurity risk prevention and control supplies for major emergent infections diseases and plant and animal diseases.

The state is to strengthen research, development, and technological reserves of drugs, gear, and other supplies for biological security. Based on their duties and division of labor, the relevant departments of the State Council are to implement measures related to the research, development, and technological reserves of drugs, gear, and other supplies for biological security.

The relevant departments of the State Council and local people's governments at the county level or above and their relevant departments shall safeguard the production, supply, and distribution of all medical aid equipment, medications, medical instruments, and other supplies necessary for emergency response to biosecurity incidents; and the departments for transport shall promptly organize and coordinate priority transport for businesses shipping them.

**Article 71:** The state is to provide effective preventative measures and medical safeguards for personnel engaged in high-risk biosecurity work such as research on highly pathogenic microbes and on-site handling of biosecurity incidents.

#### Chapter IX: Legal Responsibility

**Article 72:** Where this Law is violated by staff performing biosecurity management duties abusing their authority, derelicting their duties, twisting the law for personal gain, or otherwise violating the law in biosecurity efforts, sanctions are to be given in accordance with law.

**Article 73:** 违反本法规定，医疗机构、专业机构或者其工作人员瞒报、谎报、缓报、漏报，授意他人瞒报、谎报、缓报，或者阻碍他人报告传染病、动植物疫病或者不明原因的聚集性疾病的，由县级以上人民政府有关部门责令改正，给予警告；对法定代表人、主要负责人、直接负责的主管人员和其他直接责任人员，依法给予处分，并可以依法暂停一定期限的执业活动直至吊销相关执业证书。

Where this law is violated by the fabrication or dissemination of false biosecurity information, constituting a violation of public security administration, the public security organs are to give public security administration punishments in accordance with law.

**Article 74:** Where this law is violated by engaging in biotechnological research, development, or applications that are prohibited by the state, then based on their duties and the division of labor, the departments in charge of health, science and technology, and rural affairs of people's governments at the county level or above are to order that the illegal conduct be stopped and confiscate illegal income, technical materials, any tools, equipment, raw materials, and other items used in the illegal

activities, and give a fine of between 1,000,000 and 10,000,000 RMB, and where the value of unlawful gains is above 1,000,000, give a fine of between 10 and 20 times the value, and may prohibit them from engaging in corresponding biotechnology research, development, and applications for a set period of time or revoke their related permits; and sanction the legal representative, principle responsible person, and directly responsible managers and other directly responsible personnel in accordance with law, giving a fine of between 100,000 and 200,000 RMB, and prohibiting their engagement in corresponding biotechnology research, development, and applications for between 10 years to life, and cancelling relevant practise certificates.

**Article 75:** Where this law is violated by engaging biotechnological research and development activities without complying with state provisions and specifications on security management for biotechnology research and development, the relevant departments of people's governments at the county level or above, based on their duties and division of labor, are to order that corrections be made or give warnings, and may give a concurrent fine of between 20,000 and 200,000 RMB; where corrections are refused or serious consequences are caused, order the research and development activities to be stopped and give a concurrent fine of between 200,000 and 2,000,000 RMB.

**Article 76:** Where this Law is violated by engaging in experimental activities on pathogenic microbes outside of a laboratory at the corresponding level, or by higher-level pathogenic microbiology laboratories engaging in experimental activities on high-risk or suspected high-risk pathogenic microbes without approvals, then based on their duties and division of labor, the departments for health and rural affairs of people's governments at the county level or above are to order that the illegal conduct be stopped and oversee the destruction of the pathogens used in the experimental activities or their delivery to a preservation establishment, and give warnings; where serious consequences such as transmission or spread of infectious disease result, the legal representative, principle responsible person and directly responsible managers and other directly responsible personnel are to be removed from their posts or dismissed in accordance with law.

**Article 77:** Where this Law is violated by allowing experimental animals to enter the marketplace after use, the departments in charge of science and technology of people's governments at the county level or above are to order corrections, confiscate unlawful gains, and give a fine of between 200,000 and 1,000,000 RMB; where the value of unlawful gains is more than 200,000, give a fine of between five and ten times the value; and where the circumstances are serious, the permits are to be revoked by the departments that them.

**Article 78:** In any of the following stations where this law is violated, based on their duties and division of labor, the relevant departments of people's governments at the county level or above are to order that corrections be made, confiscate unlawful gains, and give warnings, and a fine of between 100,000 and 1,000,000 RMB may be given concurrently :

- (1) Purchasing or bringing in important equipment or special biological factors on the control list without conducting registration or without reporting for filing to the relevant departments of the State Council;
- (2) Individuals purchase or possess important equipment or special biological factors included in the control list;
- (3) Individuals set up pathogenic microbiology laboratories or engage in pathogenic microbiology laboratory activities;

(4) Enter a high-level pathogenic microorganism laboratory without the approval of the person in charge of the laboratory.

**Article 79:** Where this law is violated by collecting or preserving our nation's human genetic resources or by using our nation's human genetic resources to carry out international scientific research collaboration, the department for science and technology under the State Council is to order that the illegal conduct be stopped and confiscate illegal income and illegally collected or preserved human genetic resources, and concurrently give a fine of between 500,000 and 5,000,000 RMB, and where the value of unlawful gains is above 1,000,000, give a fine of between 5 and 10 times the value; and sanction the legal representative, principle responsible person, and directly responsible managers and other directly responsible personnel in accordance with law by prohibiting their engagement in the corresponding activity for up to 5 years.

**Article 80:** Where this law is violated by the collection or preservation of our nation's human genetic resources by foreign organizations, individuals, or the organizations they control in fact, or by providing our nation's human genetic resources abroad, the State Council department for science and technology is to order that the illegal activity be stopped, confiscate the unlawful gains and illegally collected or preserved human genetic resources, and give a concurrent fine of between 1,000,000 and 10,000,000 RMB; where the value of unlawful gains is more than 1,000,000 RMB, give a fine of between 10 to 20 times the value.

**Article 81:** Where this law is violated by bringing in foreign species without permission or authorization, then based on their duties and division of labor, the relevant departments of people's governments at the county level or above are to confiscate the imported foreign species, and give a fine of between 50,000 and 250,000 RMB.

Where this Law is violated by releasing or discarding foreign species without permission or authorization, then based on their duties and division of labor, the relevant departments of people's governments at the county level or above are to order that the released or discarded foreign species be recaptured or recovered within a set time, and a fine of between 10,000 and 50,000 RMB is to be given.

**Article 82:** Where violations of this Law constitute a crime, criminal responsibility is to be pursued in accordance with law, where it causes harms such as to people or property, civil liability is to be borne in accordance with law.

**Article 83:** Where this Law does not have provisions on unlawful biosecurity acts that violate this Law and other laws or administrative regulations do have provisions, follow those provisions.

**Article 84:** Where foreign organizations or individuals use transport, post, or carrying to bring dangerous biological factors into the country or otherwise endanger our nation's biological security, they shall be pursued for legal responsibility according to law and other necessary measures may be taken.

#### Chapter X: Supplementary Provisions

**Article 85:** The meaning of the following terms as used in this Law:

(1) Biological factors refers to animals, plants, microorganisms, biotoxins and other bioactive substances.

(2) Major new emergent infectious diseases refers to infectious diseases appearing for the first time in our country or reappearing after having been announced as extinct, or sudden outbreaks, causing

or potentially causing serious threats to the security of public health and lives, bringing on social panic, and impacting social stability.

(3) Major emergent animal diseases refers to the first appearance of animal diseases in our nation's borders or a reoccurrence after it was announced to be eradicated, or the sudden rapid transmission of a latent animal disease that has relatively high morbidity and mortality rates, causing a serious threat or danger to the security of the livestock industry, and that might also cause a threat to public health and lives.

(4) Major emergent plant diseases refers to the first appearance of plant diseases in our nation's borders or the reoccurrence of fungi, bacteria, viruses, insects, nematodes, weeds, vermin, mollusks, and other pests that cause disease with were previously announced as eradicated, or the sudden large scale rapid emergence and transmission in a local area, causing serious harm to crops, forests, and other plant life.

(5) "Research, development and application of biotechnology" refer to activities such as scientific research, technological development, and application that is engaged in so as to understand, transform, synthesize, and utilize biology through scientific and engineering principles.

(6) Pathogenic microbes refers to microorganisms that can invade humans and animals to cause infection or even contagion, including viruses, bacteria, fungi, rickettsia, parasites, and so forth.

(7) Plant pests refers to organisms such as fungi, bacteria, viruses, insects, nematodes, weeds, rodents, mollusks, and so forth that can cause harm to crops, forest trees, and other plants.

(8) Human genetic resources include both human genetic resource materials and human genetic resource information. Human genetic resource materials refers to genetic materials such as organs, tissues, and cells, that contain the human genome, genes and other genetic materials. Human genetic resource information refers to data and other information materials produced from human genetic resource materials.

(9) Microbial resistance refers to microorganisms' development of resistance to antimicrobial drugs, resulting in the inability of antimicrobial drugs to effectively control microbial infections.

(10) Biological weapons refers to microbial agents, biological agents, and biotoxins from any source or produced in any fashion that are of a type or quantity outside legitimate needs for prevention, protection, or other peaceful uses; and also includes weapons, equipment, or transport designed for using the above mentioned biological agents or biotoxins for hostile purposes or for armed conflict.

(11) Bioterrorism [or Biological Terrorism] refers to the intentional use of pathogenic microbes, biotoxins, and so forth to carry out attacks harming the health of people, plants, or animals, causing public panic, in an attempt to achieve certain political objectives.

**Article 86:** Where information related to biosecurity is a state secret, the "P.R.C. Law on the Protection of State Secrets" and other national provisions on secrecy should be referenced in implementing a secrecy management.

**Article 87:** Biological security activities of the Chinese People's Liberation Army and Chinese people's armed police forces are to be provided for separately by the Central Military Commission in accordance with the principles of this Law.

**Article 88:** This law is to take effect on April 15, 2021.