

Biosafety Law of the People's Republic of China

(October 17, 2020, Standing Committee of the 13th National People's Congress)

The 22nd meeting of the Committee adopted the resolution based on the 10th meeting held on April 26, 2024.

The Ninth Meeting of the Standing Committee of the Fourth National People's Congress on the Amendment of the Decision on...

Amend the "Agricultural Technology Extension Law of the People's Republic of China" and the "Law of the People's Republic of China on the Promotion of Agricultural Technology".

The Law of the People's Republic of China on the Protection of Minors and the Biosecurity Law of the People's Republic of China

(Decision Amendment)

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Chapter 1 General Provisions

Article 1. In order to safeguard national security and prevent and respond to biosecurity risks,

Protect people's lives and health, safeguard biological resources and the ecological environment, and promote the health of biotechnology.

Development, promoting the building of a community with a shared future for mankind, achieving harmonious coexistence between humanity and nature, and formulating...

This law.

Article 2 For the purposes of this Law, biosecurity refers to the effective prevention and response by the State to dangers.

Despite threats from biological agents and related factors, biotechnology can achieve stable and healthy development, ensuring people's livelihoods.

Life health and ecosystems are in a relatively safe and unthreatened state, in the biological field

The domain possesses the capability to safeguard national security and sustainable development.

This law applies to the following activities:

- (a) Prevention and control of major emerging and re-emerging infectious diseases and animal and plant epidemics;
- (ii) Biotechnology research, development and application;
- (III) Biosafety management of pathogenic microorganism laboratories;
- (iv) Safety management of human genetic resources and biological resources;
- (v) Preventing the invasion of alien species and protecting biodiversity;
- (vi) Addressing microbial resistance;
- (vii) Preventing bioterrorism attacks and defending against biological weapons threats;
- (viii) Other activities related to biosafety.

Article 3. Biosecurity is an important component of national security. Maintaining biosecurity...

The whole should implement the overall national security concept, coordinate development and security, and adhere to the people-centered approach.

The principles of risk prevention, categorized management, and collaborative cooperation.

Article 4 Upholding the leadership of the Communist Party of China over national biosecurity work, and establishing

Improve the national biosecurity leadership system and strengthen national biosecurity risk prevention and control.

System building to improve the country's biosecurity governance capabilities.

Article 5 The State encourages innovation in biotechnology and strengthens biosafety infrastructure and

Developing a talent pool for biotechnology, supporting the development of the bio-industry, and driving innovation to enhance the quality of life.

Improve biotechnology and enhance biosafety capabilities.

Article 6 The State shall strengthen international cooperation in the field of biosafety and fulfill its obligations under the People's Republic of China.

The Republic supports its participation in biotechnology in accordance with its obligations under international treaties concluded or acceded to.

Exchange and cooperation in international biosafety incident response, and active participation in international biosafety rules.

Research and development of [these technologies] will promote the improvement of global biosafety governance.

Article 7. People's governments at all levels and their relevant departments shall strengthen the implementation of the Biosecurity Law.

Publicity and education on laws, regulations, and biosafety knowledge should be carried out to guide grassroots self-governing organizations.

Social organizations conduct publicity on biosafety laws and regulations and biosafety knowledge to promote the whole society.

This will raise awareness of biosafety.

Relevant research institutions, medical institutions, and other enterprises and public institutions should include biological...

Safety laws and regulations and biosafety knowledge should be incorporated into education and training content to strengthen students' awareness and understanding of biosafety.

Cultivating biosafety and ethical awareness among professionals.

News media should conduct public service campaigns on biosafety laws and regulations and biosafety knowledge.

Public awareness campaigns and media scrutiny of violations of biosafety laws will enhance public understanding and protection of biosafety.

A strong sense of social responsibility.

Article 8 No unit or individual may endanger biosecurity.

Any organization or individual has the right to report acts that endanger biosecurity; upon receiving a report...

The relevant departments should handle the matter promptly and in accordance with the law.

Article 9 recognizes units and individuals who have made outstanding contributions to biosafety work.

People's governments at or above the county level and their relevant departments shall commend and reward them in accordance with national regulations.

Chapter Two: Biosafety Risk Prevention and Control System

Article 10 The central national security leadership body is responsible for national biosecurity work.

Decision-making and coordination, researching, formulating, and guiding the implementation of the national biosafety strategy and related matters.

Major policies and guidelines, coordinating major issues and important tasks related to national biosecurity.

Establish a national biosafety coordination mechanism.

Provinces, autonomous regions, and municipalities directly under the central government shall establish a coordination mechanism for biosafety work to organize and coordinate...

Supervise and promote biosafety-related work within this administrative region.

Article 11 The national biosafety coordination mechanism shall be established by the State Council's Health and Family Planning Commission.

Composed of relevant departments such as agriculture and rural affairs, science and technology, and foreign affairs, as well as relevant military agencies, and divided into...

Analyze and assess the national biosecurity situation, organize, coordinate, and supervise the advancement of relevant national biosecurity initiatives.

The National Biosafety Coordination Mechanism has established an office to coordinate related work.

The daily work.

Member units of the National Biosafety Coordination Mechanism and other relevant departments of the State Council

Each department is responsible for biosafety-related work according to its assigned duties.

Article 12 The national biosafety coordination mechanism shall establish an expert committee to provide...

Provide decision-making advice on national biosafety strategy research, policy formulation and implementation.

Relevant departments of the State Council have organized the establishment of biosafety technology consultation mechanisms in relevant fields and industries.

Consult the expert committee to provide technical support such as consultation, assessment, and demonstration for biosafety work.

support.

Article 13 Local people's governments at all levels shall be responsible for biosafety work within their respective administrative regions.

Take responsibility.

Relevant departments of local people's governments at or above the county level are responsible for biosafety according to their respective duties.

All related work.

Grassroots self-governing organizations should assist local people's governments and relevant departments.

We must do a good job in biosafety risk prevention and control, emergency response, and public education.

Relevant units and individuals should cooperate in biosafety risk prevention and emergency response.

Placement and other tasks.

Article 14 The State establishes a biosafety risk monitoring and early warning system.

The safety work coordination mechanism organizes the establishment of a national biosafety risk monitoring and early warning system, and improves...

High biosafety risk identification and analysis capabilities.

Article 15 The State establishes a biosafety risk investigation and assessment system.

The safety work coordination mechanism should regularly coordinate based on risk monitoring data, information, and other relevant data.

Organize and conduct biosafety risk surveys and assessments.

In any of the following circumstances, the relevant departments shall promptly conduct a biosafety risk assessment.

An assessment will be conducted, and necessary risk prevention and control measures will be taken in accordance with the law.

(i) Discovering potential biosafety risks through risk monitoring or receiving reports.

risk;

(ii) To determine the key areas and projects for supervision and management, formulate and adjust relevant regulations.

Biosafety-related lists or catalogs;

(iii) Major emerging and re-emerging infectious diseases, animal and plant epidemics, or other threats to biosecurity

The whole event;

(iv) Other situations that require investigation and assessment.

Article 16 The State establishes a biosafety information sharing system. National biosafety

The working coordination mechanism organizes the establishment of a unified national biosafety information platform, and relevant departments

Biosafety data, information, and other related information should be submitted to the national biosafety information platform.

Achieve information sharing.

Article 17 The State establishes a biosafety information release system. National biosafety

Overall situation, major biosafety risk warning information, major biosafety incidents and their...

Major biosafety information, such as investigation and processing information, shall be handled by the National Biosafety Coordination Agency.

Member units shall release information according to their respective responsibilities; other biosafety information shall be released by the relevant departments of the State Council.

Departments and local people's governments at or above the county level and their relevant departments shall issue such announcements in accordance with their duties and powers.

No organization or individual may fabricate or disseminate false biosafety information.

Article 18 The State establishes a biosafety list and inventory system. The State Council and its...

Relevant departments, based on the needs of biosafety work, have taken measures regarding materials and equipment related to biosafety.

Technology, activities, important biological resource data, infectious diseases, animal and plant diseases, and invasive species.

Establish and publish lists or catalogs of invasive species, and make dynamic adjustments to them.

Article 19 The State establishes a biosafety standards system. The State Council's standardization authority...

Departments and other relevant departments of the State Council shall, in accordance with their respective responsibilities, formulate and improve biosafety...

Relevant standards in the field.

The National Biosafety Coordination Mechanism organizes relevant departments to strengthen biosafety efforts in different fields.

Coordination and alignment of biosafety standards, and establishment and improvement of the biosafety standard system.

Article 20 The State establishes a biosafety review system. This system will be used for reviews of biosafety that affect or may affect [the following].

Major biological matters and activities that affect national security shall be handled by the relevant departments of the State Council.

Biosafety reviews effectively prevent and mitigate biosafety risks.

Article 21 The State establishes a unified leadership, coordinated and efficient system for ecological civilization construction.

Material safety emergency response system.

Relevant departments of the State Council shall organize the formulation of regulations on biosafety incidents in relevant fields and industries.

Emergency response plan, and conduct emergency drills and emergency response in accordance with the emergency response plan and unified deployment.

Emergency rescue and post-disaster recovery work.

Local people's governments at or above the county level and their relevant departments shall formulate, organize and guide

And urge relevant enterprises and institutions to formulate emergency response plans for biosafety incidents and strengthen emergency response.

Preparation, personnel training, and emergency drills; implementation of emergency response to biosafety incidents.

Rescue and post-disaster recovery efforts.

The Chinese People's Liberation Army and the Chinese People's Armed Police Force, in accordance with the Central Military Commission

In accordance with the orders of the meeting, we shall participate in emergency response and rescue work for biosafety incidents in accordance with the law.

Article 22 The State establishes a system for investigating and tracing the source of biosafety incidents. In the event of a major...

Emerging infectious diseases, animal and plant epidemics, and biosafety incidents of unknown origin;

The national biosafety coordination mechanism should organize and conduct investigations to trace the source of the incident and determine its nature.

Conduct a comprehensive assessment of the event's impact and provide recommendations.

Article 23 The State establishes a system for the first entry or resumption of entry after suspension.

National access system for plants, animal and plant products, and high-risk biological agents.

Personnel, means of transport, containers, goods, articles, packaging materials and entering and leaving the country

The discharge of ballast water from international vessels must comply with my country's biosafety management requirements.

Customs shall handle any biosafety risks discovered during entry, exit, and transit in accordance with the law.

Personnel, vehicles, goods, and items assessed as high-risk for biosafety should be...

When entering the country through designated border crossings, strict risk control measures shall be implemented.

Article 24 The State shall establish a system for responding to major biosafety incidents abroad.

In the event of a major biosafety incident, the customs will take emergency biosafety prevention and control measures in accordance with the law.

Measures include strengthening document verification, increasing the inspection rate, and suspending the entry of relevant personnel and means of transport.

Goods and articles entering the country. If necessary, with the approval of the State Council, temporary closures may be implemented.

Measures such as closing border crossings and sealing off relevant national borders.

Article 25. Relevant departments of people's governments at or above the county level shall carry out production in accordance with the law.

During the safety supervision and inspection of goods, the inspected units and individuals shall cooperate and truthfully explain the situation.

Furthermore, the provision of information must not be refused or obstructed.

Supervision and inspection work involves high levels of professional skills and significant challenges in law enforcement.

The work should involve biosafety professionals.

Article 26. Relevant departments of people's governments at or above the county level shall implement biosafety supervision.

In accordance with the law, the following measures may be taken during inspections:

(i) Entering the inspected unit or location or suspected of committing illegal acts related to biosafety.

To conduct on-site monitoring, investigation, inspection or verification of the premises;

(ii) Obtain information from relevant units and individuals;

(iii) To review and copy relevant documents, materials, archives, records, vouchers, etc.;

(iv) Seal off premises and facilities suspected of violating biosafety regulations;

(v) Seize tools, equipment, and related materials suspected of being used in biosafety violations.

Close the items;

(vi) Other measures stipulated by laws and regulations.

Information on violations of biosafety laws by relevant entities and individuals should be included in the national information database in accordance with the law.

Use information sharing platforms.

Chapter Three: Prevention and Control of Major Emerging and Re-emerging Infectious Diseases and Animal and Plant Epidemics

Article 27 The State Council's health, agriculture and rural affairs, forestry and grassland, and customs departments

The ecological and environmental protection authorities should establish systems for monitoring emerging and re-emerging infectious diseases, animal and plant epidemics, and entry and exit...

The border quarantine and biotechnology environmental safety monitoring network will be established, and the layout and construction of monitoring stations will be organized.

Improve the monitoring and information reporting system, conduct active monitoring and pathogen detection, and incorporate it into the national [system/information].

Biosafety risk monitoring and early warning system.

Article 28. Disease prevention and control institutions, animal disease prevention and control institutions,

Plant disease and pest prevention and control institutions (hereinafter referred to as professional institutions) shall be responsible for infectious diseases,

Active surveillance will be conducted on animal and plant diseases and unexplained diseases included in the surveillance scope, and data will be collected.

Analyze and report monitoring information to predict the occurrence of emerging and re-emerging infectious diseases and animal and plant diseases.

Popular trends.

The relevant departments of the State Council, local people's governments at or above the county level and their relevant departments shall

Early warnings should be issued promptly based on forecasts and the scope of responsibilities and authority, and corresponding prevention and control measures should be taken.

Article 29 Any unit or individual who discovers infectious diseases or animal/plant epidemics,

It should be reported to medical institutions, relevant professional organizations or departments in a timely manner.

Medical institutions, professional organizations, and their staff who discover infectious diseases or animal and plant diseases

In the event of a cluster of illnesses of unknown origin, it should be reported promptly and protective measures should be taken.

Shi.

No unit or individual may conceal, falsify, or delay reporting matters that are required to be reported according to law.

No one may fail to report, nor may they instruct others to conceal, falsify, or delay reporting, nor may they obstruct others from reporting.

Article 30 The State shall establish a joint prevention and control mechanism for major emerging and re-emerging infectious diseases and animal and plant epidemics.

Joint control mechanism.

In the event of a major emerging or re-emerging infectious disease or animal or plant epidemic, relevant laws shall apply.

In accordance with regulations and emergency plans, control measures should be taken promptly; the State Council's health and agriculture departments should...

The relevant departments in charge of agriculture, rural affairs, forestry and grassland should immediately organize a consultation and assessment meeting on the epidemic situation.

The findings of the analysis were reported to the central national security leadership and the State Council, and also communicated to the National Security Commission.

Other member units of the biosecurity work coordination mechanism and other relevant departments of the State Council.

In the event of a major emerging or re-emerging infectious disease or animal or plant epidemic, local people's governments at all levels

Unified performance of epidemic prevention and control responsibilities within this administrative region, strengthening organizational leadership, and carrying out community-based prevention and control.

Community-based prevention and control, medical treatment, mobilizing and encouraging social forces to participate in epidemic prevention and control work in a lawful and orderly manner.

do.

Article 31 The State strengthens joint efforts to combat infectious diseases and animal and plant epidemics at borders and ports.

Strengthen prevention and control capabilities, establish an international cooperation network for the prevention and control of infectious diseases and animal and plant diseases, and do our best to

Early detection and control of major emerging and re-emerging infectious diseases and animal and plant epidemics.

Article 32 The State protects wild animals, strengthens animal disease prevention, and prevents animal...

Transmission of infectious diseases originating from the source.

Article 33 The State strengthens the supervision of the use of antibiotics and other antimicrobial drugs.

And the management of residues, supporting basic research and technological breakthroughs in addressing antimicrobial resistance.

The health and wellness departments of people's governments at or above the county level shall strengthen supervision of medical institutions.

Guidance and supervision on rational drug use, and measures to prevent the irrational use of antimicrobial drugs.

Use. The agricultural and rural affairs and forestry and grassland departments of people's governments at or above the county level shall strengthen their oversight of...

Guidance and supervision of rational pesticide use in agricultural production, and measures to prevent the use of antimicrobial drugs.

To reduce the improper use of [the substance], we must reduce its residues in the agricultural production environment.

The State Council's relevant ministries and departments in charge of health, agriculture and rural affairs, forestry and grassland, and ecology and environment, etc.

Departments and drug regulatory authorities shall, according to their respective responsibilities, assess antimicrobial drug residues.

To mitigate the harm to human health and the environment, an evaluation system for antimicrobial drug contaminant indicators should be established.

system.

Chapter 4 Safety of Biotechnology Research, Development and Application

Article 34 The State strengthens its oversight of biotechnology research, development and application activities.

Safety management prohibits activities that endanger public health, damage biological resources, or disrupt ecosystems.

Biotechnology research, development and application activities that threaten biosafety, including those related to biodiversity.

move.

Those engaged in biotechnology research, development, and application activities should comply with ethical principles.

Article 35 Entities engaged in biotechnology research, development and application activities shall

When responsible for the safety of biotechnology research, development, and application within the organization, and taking biosafety measures...

Comprehensive risk prevention and control measures, including the development of biosafety training, follow-up inspections, and regular reporting.

Establish systems and strengthen process management.

Article 36 The State implements classified management of biotechnology research and development activities.

Reasonable. Based on the degree of risk posed to public health, industry and agriculture, and the ecological environment.

The risk level is categorized into three levels: high-risk, medium-risk, and low-risk.

kind.

The risk classification standards and list for biotechnology research and development activities are formulated by the State Council Science and Technology Commission.

The relevant departments in charge of technology, health, agriculture and rural affairs, etc., shall, in accordance with their respective responsibilities, work with the State Council

Other relevant departments of the institute shall formulate, adjust and publish the relevant regulations.

Article 37 Those engaged in biotechnology research and development activities shall comply with national regulations.

Safety management standards for biotechnology research and development.

Those engaged in biotechnology research and development activities should conduct risk category assessments and closely monitor the information.

Pay close attention to changes in risks and take timely countermeasures.

Article 38. Those engaged in high-risk or medium-risk biotechnology research and development activities,

It should be carried out by a legal entity established in accordance with the law within the territory of my country, and obtain approval or [other necessary documents] in accordance with the law.

Those who register must do so.

Those engaged in high-risk or medium-risk biotechnology research and development activities should conduct risk assessments.

Risk assessment, development of risk prevention and control plans and emergency response plans for biosafety incidents, to reduce research,

Risks associated with the implementation of development activities.

Article 39 The State shall provide for important equipment and special biological materials related to biosafety.

Factors are subject to traceability management. This includes the purchase or import of key equipment and special equipment listed in the control list.

Special biological agents should be registered to ensure traceability and reported to the relevant departments of the State Council.

Filing.

Individuals are prohibited from purchasing or possessing important equipment and special living supplies listed in the control list.

Material factors.

Article 40. Clinical research on new biomedical technologies shall be subject to ethical review.

The investigation shall be conducted within a qualified medical institution; human clinical trials shall be carried out.

The work should be performed by qualified health professionals.

Article 41 The relevant departments of the State Council shall, in accordance with the law, supervise the application of biotechnology activities.

If a biosafety risk is identified through follow-up assessments, effective remedial measures should be taken promptly.

and control measures.

Chapter 5 Biosafety in Pathogenic Microorganism Laboratories

Article 42 The State strengthens the management of biosafety in pathogenic microorganism laboratories.

Establish and implement unified laboratory biosafety standards. Pathogenic microorganism laboratories should meet [the relevant requirements].

It complies with national standards and requirements for biosafety.

Those engaged in pathogenic microorganism experiments must strictly adhere to relevant national standards and regulations.

Laboratory technical specifications and operating procedures should be followed, and safety precautions should be taken.

Article 43 The State, based on the infectivity of pathogenic microorganisms and their effects on humans after infection,

The severity of harm caused by individual animals or groups is used to classify and manage pathogenic microorganisms.

Collecting and preserving samples of highly pathogenic or suspected highly pathogenic microorganisms

Activities involving the storage and transportation of [materials] must meet certain conditions and comply with biosafety management regulations.

The specific measures shall be formulated by the State Council's health and agriculture and rural affairs departments.

Article 44 The establishment of a pathogenic microorganism laboratory shall be subject to approval or [requirement/requirement] in accordance with the law.

Those who register must do so.

Individuals are prohibited from establishing pathogenic microorganism laboratories or engaging in pathogenic microorganism experiments.

Activity.

Article 45. The State, based on the level of biosafety protection against pathogenic microorganisms,

Laboratories dealing with pathogenic microorganisms are subject to tiered management.

Experiments involving pathogenic microorganisms should be conducted in laboratories of the appropriate level. (Low level)

Level-3 pathogenic microorganism laboratories shall not engage in activities that are required by the National Pathogenic Microorganism Catalogue.

Pathogenic microorganism experiments conducted in high-level pathogenic microorganism laboratories.

Article 46 High-level pathogenic microorganism laboratories engage in the production of highly pathogenic or

Experimental activities involving suspected highly pathogenic microorganisms shall be approved by the health department of the provincial-level or higher people's government.

The experiment must be approved by the relevant health or agricultural and rural affairs authorities, and the details of the experiment must be reported to the approving department.

Door report.

For pathogenic microorganisms that have not yet been discovered or have been declared eradicated in my country, without approval

They are not allowed to engage in related experimental activities.

Article 47 Pathogenic microorganism laboratories shall take measures to strengthen the laboratory

Animal management, preventing laboratory animals from escaping, and handling used laboratory animals in accordance with national regulations.

Regulations stipulate the need for harmless disposal and traceability of laboratory animals. The disposal of used laboratory animals is prohibited.

Animals being tested are entering the market.

Pathogenic microorganism laboratories should strengthen the management of experimental waste in accordance with the law.

Wastewater, waste gas, and other wastes are disposed of, and measures are taken to prevent pollution.

Article 48 The establishing unit of the pathogenic microorganism laboratory is responsible for the laboratory's...

Biosafety management includes establishing scientific and rigorous management systems and regularly reviewing relevant biosafety information.

The implementation of all regulations was inspected, including laboratory facilities, equipment, and materials.

Inspect, maintain, and update it to ensure it meets national standards.

The legal representative and laboratory director of the entity establishing the pathogenic microorganism laboratory

Responsible for the biosafety of the laboratory.

Article 49 The entity establishing a pathogenic microorganism laboratory shall establish and complete...

Establish sound security systems and implement security measures to protect the laboratory and its pathogenic microorganisms.

Safety of objects.

The state has strengthened security measures for high-level pathogenic microorganism laboratories.

The original microbiology laboratory should accept the relevant laboratory security work of public security organs and other departments.

Supervision and guidance should be provided to strictly prevent the leakage, loss, theft, or misappropriation of highly pathogenic microorganisms.

Rob.

The state has established a review system for personnel entering high-level pathogenic microorganism laboratories.

Personnel in high-level pathogenic microorganism laboratories must be approved by the laboratory director. (Regarding...)

Approval will not be granted if it could affect laboratory biosafety; for those approved, measures should be taken...

Safety and security measures.

Article 50 The establishment unit of the pathogenic microorganism laboratory shall formulate biosafety regulations.

A comprehensive emergency response plan is in place, and regular personnel training and emergency drills are conducted. In the event of a high-risk incident...

Leakage, loss, theft, robbery, or other biosafety risks of pathogenic microorganisms.

If necessary, control measures should be taken promptly in accordance with the provisions of the emergency plan, and in accordance with national regulations.

Final report.

Article 51 The provincial people's government where the pathogenic microorganism laboratory is located and its

Health authorities should strengthen the allocation of infectious disease medical resources in the locations of laboratories.

To improve the medical treatment capacity for infectious diseases.

Article 52 Enterprises shall ensure the safety of production workshops involving the handling of pathogenic microorganisms.

Biosafety management shall be carried out in accordance with the relevant regulations for pathogenic microorganism laboratories and other biosafety provisions.

Management is conducted in a standardized manner.

Biosafety involving the handling of biotoxins, plant pests, and other biological agents

The construction and management of the entire laboratory shall be carried out in accordance with the relevant regulations for pathogenic microorganism laboratories.

Chapter Six Human Genetic Resources and Biological Resource Security

Article 53 The State shall strengthen the collection of human genetic resources and biological resources in my country.

The management and supervision of activities such as collection, preservation, utilization, and provision to foreign entities are essential to safeguarding human genetic resources.

Resource and biological resource security.

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

Article 54 The State shall conduct surveys of human genetic resources and biological resources.

The State Council's health authority organized and carried out a survey of my country's human genetic resources.

Formulate procedures for the declaration and registration of important genetic pedigrees and human genetic resources in specific regions.

The State Council's health, science and technology, natural resources, ecological environment, and agriculture departments

Village, forestry and grassland, and traditional Chinese medicine authorities, according to their respective responsibilities, organized and carried out biological resource management.

Source surveys and the formulation of procedures for the declaration and registration of important biological resources.

Article 55 The collection, preservation, utilization, and provision of my country's human genetic resources to foreign entities

Sources must comply with ethical principles and must not endanger public health, national security, or social order.

Common interests.

Article 56 The following activities shall be subject to approval by the health and wellness department of the State Council.

Department approved:

(i) Collecting important genetic pedigrees in my country, human genetic resources from specific regions, or

Collect human genetic resources of the types and quantities specified by the health and wellness authorities under the State Council;

(ii) Preserving my country's human genetic resources;

(III) Conducting international scientific research cooperation using my country's human genetic resources;

(iv) Transporting, mailing, or carrying human genetic resources materials out of the country.

The preceding provisions do not include clinical diagnosis and treatment, blood collection and supply services, investigation and handling of illegal and criminal activities,

The collection and preservation of human genetic resources for purposes such as doping control and funeral services, and related research.

Closing activities.

In order to obtain marketing authorization for relevant drugs and medical devices in my country, clinical trials are required.

The institution utilizes my country's human genetic resources to conduct international collaborative clinical trials, which do not involve human subjects.

Genetic resources do not require approval to be exported; however, approval must be obtained before conducting clinical trials.

The types, quantities, and uses of the human genetic resources to be used shall be submitted to the State Council's health authority.

Departmental filing.

Foreign organizations, individuals, and their established or de facto controlled entities are prohibited from operating within China.

my country's human genetic resources shall be collected and preserved within the country, and shall not be provided to foreign countries.

resource.

Article 57 stipulates that my country's human genetic resources information will be shared with overseas organizations and individuals.

If the institution it establishes or actually controls provides or makes available for use, it shall report to the State Council.

The health authorities shall report in advance and submit backup information.

Article 58. The collection, preservation, utilization, and transportation of precious and endangered species out of my country shall be prohibited.

Endemic species and their individuals, organs, tissues, and cells that can be used for regeneration or reproduction.

Genetic resources such as cells and genes should be handled in accordance with relevant laws and regulations.

Foreign organizations, individuals, and their established or de facto controlled entities obtain and utilize my

Biological resources within the country must be approved in accordance with the law.

Article 59. International scientific research cooperation utilizing my country's biological resources should be conducted in accordance with relevant regulations.

When approval is obtained in accordance with the law.

Utilizing my country's human genetic and biological resources to conduct international scientific research cooperation

It is essential to ensure that Chinese institutions and their researchers participate in the research process in a full and substantive manner, in accordance with...

Legal sharing of relevant rights.

Article 60 The State shall strengthen the prevention and response to invasive alien species and protect the ecosystem.

Biodiversity. The agricultural and rural affairs department of the State Council, in conjunction with other relevant departments of the State Council, formulated...

Establish a list of invasive alien species and management methods.

Relevant departments of the State Council, in accordance with their respective responsibilities, have strengthened the investigation and control of invasive alien species.

The work includes investigation, monitoring, early warning, control, assessment, removal, and ecological restoration.

No organization or individual may, without approval, introduce, release, or discard foreign objects.

Species from elsewhere.

Chapter Seven: Preventing Bioterrorism and Biological Weapons Threats

Article 61 The State shall take all necessary measures to prevent bioterrorism and biological warfare.

Weapon threat.

The development, manufacture, or other acquisition, storage, possession, and use of biological materials are prohibited.

Physical weapons.

It is prohibited to instigate, fund, or assist others in developing, manufacturing, or otherwise using [the technology/method].

He acquired biological weapons through other means.

Article 62. The relevant departments of the State Council shall formulate, amend, and promulgate regulations that can be used for the purpose of production.

Biological terrorism, organisms, biotoxins, equipment or technology used to create biological weapons

The list should be strengthened to prevent its use in the manufacture of biological weapons or for terrorist purposes.

Article 63. Relevant departments of the State Council and relevant military organs shall, in accordance with their respective duties...

Work to strengthen the control over organisms that could be used for bioterrorism, the manufacture of biological weapons, and other biological agents.

Import, export, acquisition, manufacture, transfer and release of toxins, equipment or technology

Monitor and investigate activities such as releases, and take necessary preventive and response measures.

Article 64. Relevant departments of the State Council, provincial people's governments and their relevant departments

Responsible for organizing the treatment and resettlement of personnel after bioterrorism attacks or biological weapons attacks.

Work includes environmental disinfection, ecological restoration, safety monitoring, and restoration of social order.

Relevant departments of the State Council, provincial people's governments and their relevant departments should provide effective guidance

Public opinion should provide scientific and accurate reporting of bioterrorism attacks and biological weapons attacks.

Information on evacuation, relocation, and emergency shelter should be released in a timely manner to support emergency response and recovery.

Long-term environmental and health monitoring will be conducted on the contaminated areas and individuals.

Article 65 The State organizes and carries out investigations into biological weapons left over from war within its territory.

An investigation into its harmful consequences and potential impacts.

The state organizes the construction of facilities for storing and disposing of biological weapons left over from war, to ensure the defense against war.

The safe disposal of remaining biological weapons.

Article 66 The State shall formulate development plans for biosafety and strengthen biosafety.

Comprehensive capacity building to improve the ability and level of response to biosafety incidents.

People's governments at or above the county level shall support the development of biosafety undertakings and, in accordance with the division of responsibilities...

The government budget will include expenditures supporting the development of the following biosafety initiatives:

- (a) Construction and operation of the monitoring network;
- (ii) The reserve of emergency response and prevention and control materials;
- (iii) Construction and operation of critical infrastructure;
- (iv) Research and development of key technologies and products;
- (v) Investigation and preservation of human genetic resources and biological resources;
- (vi) Other important biosafety undertakings as stipulated by laws and regulations.

Article 67 The State shall take measures to support scientific and technological research on biosafety and strengthen biosafety.

Research on biosecurity risk prevention and control technologies, integrating superior strengths and resources, and establishing multiple

A collaborative research mechanism involving multiple disciplines and departments is needed to advance core and critical research in biosafety.

The scientific output and transformation application of technological and major defense products will improve biosecurity.

Skills guarantee ability.

Article 68 The State shall make overall plans for the construction of national biosafety infrastructure.

Relevant departments of the State Council, in accordance with their respective responsibilities, will accelerate the development of bioinformatics and human genetic resources.

Preservation, strain (virus) preservation, animal and plant genetic resource preservation, high-level pathogenic microorganisms

Establish a national strategic resource platform for biosafety, including biological laboratories, and create a sharing and utilization mechanism.

This system provides strategic guarantees and support for scientific and technological innovation in biosafety.

Article 69. Relevant departments of the State Council shall, in accordance with their respective responsibilities, strengthen basic biological research.

To cultivate scientific research talent and professional and technical personnel in the biological field, and to promote basic biological science.

Discipline development and scientific research.

Personnel working in key positions within the national biosafety infrastructure should possess the following qualifications:

The required qualifications and related information should be filed with the relevant departments of the State Council and accepted by the relevant authorities.

Training.

Article 70 The State strengthens its efforts in preventing and controlling major emerging and re-emerging infectious diseases, animal and plant epidemics, etc.

Material reserves for the prevention and control of material safety risks.

The state strengthens the research, development, and technology of emergency medicines, equipment, and other supplies for biosafety.

Technical reserves. Relevant departments of the State Council, according to their respective responsibilities, shall ensure the availability of emergency medicines for biosafety.

Measures related to the research, development, and technological reserves of equipment and other materials.

Relevant departments of the State Council and local people's governments at or above the county level and their relevant departments should

When ensuring the availability of medical equipment and medicines needed for emergency response to biosafety incidents,

The production, supply, and allocation of medical devices and other supplies; the transportation authorities shall promptly...

The relevant departments will organize and coordinate with transportation operators to prioritize delivery.

Article 71 The State regulates activities involving experiments with highly pathogenic microorganisms and biological agents.

Personnel engaged in high-risk biosafety work, such as on-site handling of biosafety incidents, should be provided with effective [services/support].

Protective measures and medical care.

Chapter Nine Legal Liability

Article 72. Violations of this Law in the performance of biosafety management duties

Personnel who abuse their power, neglect their duties, engage in favoritism or malpractice, or otherwise commit other misconduct in biosafety work.

Those who commit illegal acts shall be punished in accordance with the law.

Article 73. Medical institutions, professional organizations, or their employees who violate the provisions of this Law shall be held accountable.

Staff members who conceal, falsify, delay, or omit reports, or who instruct others to conceal, falsify, or delay reports,

Or obstructing others from reporting infectious diseases, animal or plant diseases, or unexplained outbreaks of disease.

Those who are ill shall be ordered to rectify the situation and given a warning by the relevant departments of the people's government at or above the county level; those who violate the law shall be dealt with accordingly.

Designated representative, principal responsible person, directly responsible supervisor and other directly responsible persons

Employees who violate the law will be subject to disciplinary action, and their professional activities may be suspended for a certain period of time or even terminated.

Sell relevant professional certificates.

Violating this law by fabricating or disseminating false biosafety information constitutes a violation.

Those who commit acts that violate public security regulations shall be subject to administrative penalties by the public security authorities in accordance with the law.

Article 74. Anyone who violates the provisions of this Law by engaging in biotechnology research prohibited by the State...

Research, development, and application activities shall be conducted by the health and science and technology departments of the people's governments at or above the county level.

According to their respective responsibilities, the relevant departments in charge of agriculture and rural affairs shall order the cessation of illegal activities and confiscate the goods.

Illegal proceeds, technical data, and tools, equipment, raw materials, etc. used in illegal activities

For illegal activities, a fine of between one million and ten million yuan shall be imposed, and illegal gains of one million yuan shall be subject to a fine of between one million and ten million yuan.

Those who violate the above regulations shall be fined between ten and twenty times the amount of their illegal gains, and may also be prohibited from engaging in such activities according to law.

Restricting individuals from engaging in relevant biotechnology research, development, and application activities for a certain period, and revoking their licenses.

Relevant licenses and permits; [regarding] the legal representative, principal responsible person, and directly responsible supervisor.

Employees and other directly responsible personnel shall be punished in accordance with the law, with fines ranging from 100,000 to 200,000 yuan.

The following fines may result in a ten-year ban or a lifetime ban from engaging in relevant biotechnology research and development.

For related application activities, the relevant professional certificates will be revoked in accordance with the law.

Article 75. Violating the provisions of this Law by engaging in biotechnology research and development activities

Those who fail to comply with national regulations on the safety management of biotechnology research and development shall be punished by the people's government at or above the county level.

Relevant government departments, according to their respective responsibilities, may order rectification, issue warnings, and may impose two penalties concurrently.

A fine of between 10,000 and 200,000 yuan; failure to rectify the situation or causing serious consequences.

The organization was ordered to cease its research and development activities and was fined between 200,000 and 2 million yuan.

payment.

Article 76. Violating the provisions of this Law by engaging in pathogenic microorganism experiments without obtaining a certificate or permit is prohibited.

The procedure was performed in a laboratory of the appropriate level, or in a high-level pathogenic microorganism laboratory without approval.

Those engaged in experimental activities involving highly pathogenic or suspected highly pathogenic microorganisms shall be subject to the supervision of county-level authorities.

The local people's government's health and agriculture and rural affairs departments, according to their respective responsibilities, are responsible for...

Order them to cease their illegal activities and supervise the proper disposal of pathogenic microorganisms used in their experiments.

The item will be handed over to a preservation institution and a warning will be issued; if it causes the spread or outbreak of infectious diseases or other serious consequences...

The consequences will be borne by the legal representative, principal responsible person, directly responsible supervisor and their associates.

Those directly responsible were given disciplinary punishments of dismissal and expulsion in accordance with the law.

Article 77. Violating the provisions of this Law by releasing used laboratory animals into the market.

If so, the science and technology administrative department of the people's government at or above the county level shall order rectification and confiscate the illegal gains.

The illegal gains shall be subject to a fine of not less than 200,000 yuan and not more than 1 million yuan, and the illegal gains shall not exceed 200,000 yuan.

For amounts exceeding 10,000 yuan, a fine of five to ten times the illegal gains will be imposed; in serious cases...

If so, the issuing department shall revoke the relevant license.

Article 78. Anyone who violates the provisions of this Law by committing any of the following acts shall be punished by the county-level authorities or above.

According to their respective responsibilities, the relevant departments of the municipal people's government ordered rectification and confiscated the illegal gains.

A warning may be issued, and a fine of between 100,000 and 1 million yuan may be imposed concurrently.

(i) Purchasing or importing important equipment or special biological agents listed in the control list

The child was not registered or filed with the relevant department of the State Council;

(ii) Individuals purchasing or possessing important equipment or special equipment listed in the control list

Biological factors;

(iii) Individuals who establish pathogenic microorganism laboratories or engage in pathogenic microorganism experiments

Activity;

(iv) Entering high-level pathogenic microorganism experiments without the approval of the laboratory director.

room.

Article 79. Anyone who violates the provisions of this Law by collecting or preserving Chinese nationals' personal information without approval.

Human genetic resources or international scientific research cooperation using my country's human genetic resources

The State Council's health and wellness department shall order the cessation of the illegal activity and confiscate the illegal proceeds.

Those who illegally collect or preserve human genetic resources shall be fined between 500,000 and 5 million yuan.

A fine of less than 100,000 yuan shall be imposed; if the illegal gains exceed 1 million yuan, a fine of five times the illegal gains shall be imposed.

A fine of up to ten times the amount mentioned above; in serious cases, the legal representative and principal responsible person shall be subject to penalties.

The directly responsible supervisors and other directly responsible personnel shall be punished in accordance with the law, with a term of five years.

Engaging in related activities is prohibited within the premises.

Article 80. Any foreign organization or individual that violates the provisions of this Law, or whose establishment or operation is prohibited by law, shall be subject to penalties.

Internationally controlled institutions collect and preserve human genetic resources within my country's territory, or provide them to [other entities].

Those who provide human genetic resources to my country from overseas shall be ordered by the health and health administration department of the State Council to take action.

Cease all illegal activities, confiscate all illegal gains and illegally collected and preserved human genetic resources.

A fine of between one million and ten million yuan shall be imposed; if the illegal gains exceed one million yuan...

Those who violate the law will be subject to a fine of ten to twenty times their illegal gains.

Article 81. Anyone who violates the provisions of this Law by introducing alien species without approval.

Those that are illegally introduced shall be confiscated by the relevant departments of the people's governments at or above the county level according to their respective responsibilities.

Those who violate the regulations will be subject to a fine of between 50,000 and 250,000 yuan.

Anyone who violates this law by releasing or discarding an invasive species without approval shall be subject to penalties.

The relevant departments of the people's governments at or above the county level shall, according to their respective responsibilities, order the capture and repatriation of the animals within a specified time limit.

Anyone who releases or discards invasive species will be fined between 10,000 and 50,000 yuan.

Article 82 Anyone who violates the provisions of this Law and commits a crime shall be investigated for criminal liability in accordance with the law.

Anyone who causes personal injury, property damage, or other harm shall bear civil liability in accordance with the law.

Article 83. Violations of biosafety provisions of this Law, where not specifically addressed in this Law...

Legal liability shall be determined, and if other relevant laws and administrative regulations provide otherwise, those provisions shall apply.

Article 84. Foreign organizations or individuals who transport, mail, or carry dangerous goods...

Those who allow biological agents to enter the country or otherwise endanger my country's biosecurity will be prosecuted according to law.

Legal responsibility, and may take other necessary measures.

Chapter Ten Supplementary Provisions

Article 85 The following terms in this Law shall have the following meanings:

(a) Biological factors refer to animals, plants, microorganisms, biotoxins and their derivatives.

It contains bioactive substances.

(ii) Major emerging and re-emerging infectious diseases refer to those that have appeared for the first time or have already occurred within the territory of my country.

If an event that has been declared eradicated recurs, or occurs suddenly, causing or potentially causing harm to public health...

Infectious diseases that seriously endanger health and safety, cause social panic, and affect social stability.

(III) Major emerging and sudden outbreaks of animal epidemics refer to the first occurrence of such an epidemic within the territory of my country or

Animal diseases that have been declared eradicated may recur, or have high morbidity and mortality rates.

The sudden outbreak and rapid spread of latent animal diseases pose a serious threat to the safety of livestock production.

Threats, dangers, and situations that may endanger public health and safety.

(iv) Major emerging and re-emerging plant epidemics refer to the first occurrence of such an epidemic within the territory of my country or

Fungi, bacteria, viruses, insects, nematodes, and other pests that have been declared eradicated and seriously harm plants

Weeds, rodents, mollusks, etc., can cause pests and diseases to recur, or local harmful organisms may suddenly appear.

However, it occurred on a large scale and spread rapidly, causing serious damage to crops, trees, and other plants.

The situation.

(v) Biotechnology research, development and application refers to the application of scientific and engineering principles...

Scientific research and technological development related to the understanding, modification, synthesis, and utilization of biological organisms.

Applications and other activities.

(vi) Pathogenic microorganisms refer to those that can invade humans and animals, causing infection or even transmission.

The microorganisms that cause disease include viruses, bacteria, fungi, rickettsiae, parasites, etc.

(vii) Plant pests refer to organisms that can cause damage to crops, trees, and other plants.

Harmful fungi, bacteria, viruses, insects, nematodes, weeds, rodents, and mollusks.

Organisms such as...

(viii) Human genetic resources, including human genetic resource materials and human genetic resources

Source information. Human genetic resource materials refer to genetic materials containing the human genome, genes, and other genetic material.

Genetic material such as organs, tissues, and cells. Human genetic resource information refers to the use of...

Information and data generated from human genetic resources.

(ix) Microbial resistance refers to the development of resistance in microorganisms to antimicrobial drugs.

This leads to antimicrobial drugs being unable to effectively control microbial infections.

(x) Biological weapons refer to those whose type and quantity do not fall under the category of prevention, protection, or other biological weapons.

Microorganisms produced from any source or by any means that are legitimately needed for his peaceful purposes

Agents, other biological agents, and biotoxins; also including those for the purpose of disposing of the aforementioned biological agents and biotoxins.

Weapons, equipment or delivery vehicles designed for use in hostile purposes or armed conflict

Tool.

(xi) Bioterrorism refers to the deliberate use of pathogenic microorganisms or biotoxins.

Such attacks, which harm human or animal health, cause social panic, and attempt to achieve [goal/goal], are intended to [achieve/do something].

Actions taken for specific political purposes.

Article 86. If biosafety information constitutes a state secret, it shall be handled in accordance with the relevant provisions of the "Law of the People's Republic of China on the Protection of Biological Safety".

The People's Republic of China Law on Guarding State Secrets and other relevant state regulations on confidentiality shall be implemented to ensure...

Strict management.

Article 87 The People's Liberation Army and the People's Armed Police Force

The Central Military Commission shall separately stipulate the activities related to material security in accordance with the principles provided in this law.

Article 88 This Law shall come into force on April 15, 2021.