Regulations on the Biosafety Administration of Pathogenic Microorganism Laboratories of China (the PRC)

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Promulgated by Order No. 424 of the State Council of the People's Republic of China on November 12, 2004; amended for the first time in accordance with the Decision of the State Council on Amending Certain Administrative Regulations on February 6, 2016; amended for the second time in accordance with the Decision of the State Council on Amending and Repealing Certain Administrative Regulations on March 19, 2018; amended for the third time in accordance with the Decision of the State Council on Amending and Repealing Certain Administrative Regulations on December 6, 2024; amended for the fourth time in accordance with the Decision of the State Council on Amending and Repealing Certain Administrative Regulations on August 8, 2026

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Chapter I — General Provisions

Article 1 — These Regulations are formulated to strengthen the biosafety administration of pathogenic microorganism laboratories (hereinafter "laboratories") and to protect the health of laboratory staff and the public.

Article 2 — These Regulations apply to the biosafety administration of laboratories within the territory of the People's Republic of China and of the experimental activities they conduct.

For the purposes of these Regulations, "pathogenic microorganisms" means microorganisms capable of causing disease in humans or animals.

For the purposes of these Regulations, "experimental activities" means research, teaching, testing, diagnosis and other activities conducted by laboratories in relation to pathogenic microorganism strains (viruses) and samples.

Article 3 — The health competent department of the State Council is in charge of the biosafety supervision of laboratories and their experimental activities relating to human health.

The veterinary competent department of the State Council is in charge of the biosafety supervision of laboratories and their experimental activities relating to animals.

Other relevant departments of the State Council are responsible, within the scope of their respective duties, for the biosafety administration of laboratories and their experimental activities.

Local people's governments at or above the county level and their relevant departments are responsible, within the scope of their respective duties, for the biosafety administration of laboratories and their experimental activities.

Article 4 — The State implements classified administration of pathogenic microorganisms and graded administration of laboratories.

Article 5 — The State implements uniform laboratory biosafety standards. Laboratories shall conform to national standards and requirements.

Article 6 — The units establishing laboratories and their competent departments are responsible for the administration of the routine activities of laboratories, and assume the duties of establishing and improving safety administration systems, inspecting and maintaining experimental facilities and equipment, and controlling laboratory infections.

Chapter II — Classification and Administration of Pathogenic Microorganisms

Article 7 — The State classifies pathogenic microorganisms into four categories according to their infectivity and the degree of harm they cause to individuals or groups after infection:

Category 1 pathogenic microorganisms are microorganisms capable of causing very serious diseases in humans or animals, and microorganisms that China has not yet discovered or has declared eradicated.

Category 2 pathogenic microorganisms are microorganisms capable of causing serious diseases in humans or animals and relatively easily transmitted, directly or indirectly, between humans, between animals and humans, or between animals.

Category 3 pathogenic microorganisms are microorganisms capable of causing diseases in humans or animals, but which generally do not constitute serious harm to humans, animals or the environment, have limited transmission risk, rarely cause serious disease after laboratory infection, and for which effective treatment and prevention measures exist.

Category 4 pathogenic microorganisms are microorganisms that do not generally cause disease in humans or animals.

Category 1 and Category 2 pathogenic microorganisms are collectively referred to as highly pathogenic microorganisms.

Article 8 — The catalogue of pathogenic microorganisms transmissible between humans shall be formulated, adjusted and published by the health competent department of the State Council in consultation

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with the relevant departments of the State Council; the catalogue of pathogenic microorganisms transmissible between animals shall be formulated, adjusted and published by the veterinary competent department of the State Council in consultation with the relevant departments of the State Council.

Article 9 — The collection of pathogenic microorganism samples shall meet the following conditions:

(1) having equipment commensurate with the biosafety protection level required for collecting the pathogenic microorganism samples;

(2) having staff members with the relevant professional knowledge and operational skills;

(3) having effective measures to prevent the spread and infection of pathogenic microorganisms; and

(4) having technical methods and means to ensure the quality of pathogenic microorganism samples.

Staff members collecting highly pathogenic microorganism samples shall prevent the spread and infection of pathogenic microorganisms during collection, and make detailed records of the source, collection process and methods of the samples.

Article 10 — The transport of highly pathogenic microorganism strains (viruses) or samples shall be by land transport; where there is no land passage and water transport is necessary, transport may be by water; in emergencies, or where highly pathogenic microorganism strains (viruses) or samples need to be transported abroad, transport may be by civil aviation.

Article 11 — The transport of highly pathogenic microorganism strains (viruses) or samples shall meet the following conditions:

(1) the purpose of transport, the use of the highly pathogenic microorganisms, and the receiving unit conform to the provisions of the health competent department or the veterinary competent department of the State Council;

(2) the containers of the highly pathogenic microorganism strains (viruses) or samples shall be sealed, and the containers or packaging materials shall also meet the requirements of being waterproof, damage-proof, leak-proof, and resistant to high or low temperatures and high pressure; and

(3) the containers or packaging materials shall bear the biohazard markings, warning language and reminder language prescribed by the health competent department or the veterinary competent department of the State Council.

The transport of highly pathogenic microorganism strains (viruses) or samples shall be subject to the approval of the health competent department or the veterinary competent department of the people's government at or above the provincial level. Where transport is within the administrative region of a province, autonomous region or municipality directly under the Central Government, it shall be approved by the health competent department or the veterinary competent department of the people's government of that province, autonomous region or municipality; where transport across provinces, autonomous regions or municipalities directly under the Central Government or transport abroad is required, it shall be preliminarily reviewed by the health competent department or the veterinary competent department of the people's government of the province, autonomous region or municipality directly under the Central Government at the place of departure, and then reported to the health competent department or the veterinary competent department of the State Council for approval.

Where an entry-exit inspection and quarantine institution needs to transport pathogenic microorganism samples in the course of inspection and quarantine, it shall be approved by the entry-exit inspection and quarantine department of the State Council, which shall simultaneously notify the health competent department or the veterinary competent department of the State Council.

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Where highly pathogenic microorganism strains (viruses) or samples are transported by civil aviation, in addition to obtaining the approvals prescribed in paragraphs 2 and 3 of this Article, approval shall also be obtained from the civil aviation competent department of the State Council.

The relevant competent departments shall review the application materials submitted by applicants for the transport of highly pathogenic microorganism strains (viruses) or samples, and shall immediately approve those that meet the conditions prescribed in paragraph 1 of this Article.

Article 12 — The transport of highly pathogenic microorganism strains (viruses) or samples shall be escorted by no fewer than two dedicated persons, who shall take corresponding protective measures.

Relevant units or individuals shall not transport pathogenic microorganism strains (viruses) or samples by public electric buses, trams or urban rail.

Article 13 — Where highly pathogenic microorganism strains (viruses) or samples need to be transported by public transport such as railway, highway or civil aviation, the carrier shall transport them on the strength of the approval documents prescribed in Article 11 of these Regulations.

The carrier shall, together with the escorting personnel, take measures to ensure the safety of the highly pathogenic microorganism strains (viruses) or samples transported, and strictly prevent theft, robbery, loss or leakage.

Article 14 — The strain (virus) preservation centers or specialized laboratories designated by the health competent department or the veterinary competent department of the State Council (hereinafter "preservation institutions") undertake the task of centralized storage of pathogenic microorganism strains (viruses) and samples.

Preservation institutions shall, in accordance with the provisions of the health competent department or the veterinary competent department of the State Council, store the pathogenic microorganism strains (viruses) and samples submitted by laboratories, and provide pathogenic microorganism strains (viruses) and samples to laboratories.

Preservation institutions shall formulate strict safety custody systems, keep records of the entry, exit and storage of pathogenic microorganism strains (viruses) and samples, establish an archive system, and designate dedicated personnel to be responsible. Highly pathogenic microorganism strains (viruses) and samples shall be stored separately in dedicated warehouses or dedicated cabinets.

Preservation institutions shall not charge any fees for storing or providing pathogenic microorganism strains (viruses) and samples, and their funds shall be guaranteed by the finance department at the corresponding level within the unit budget.

The administrative measures for preservation institutions shall be formulated by the health competent department of the State Council in conjunction with the veterinary competent department of the State Council.

Article 15 — Preservation institutions shall provide highly pathogenic microorganism strains (viruses) and samples to laboratories and register them, on the strength of the approval documents for engaging in highly pathogenic microorganism-related experimental activities obtained by the laboratories in accordance with these Regulations, or the laboratory filing vouchers issued by the health competent department or the veterinary competent department of the people's government of a city divided into districts.

Article 16 — After the completion of relevant experimental activities, laboratories shall, in accordance with the provisions of the health competent department or the veterinary competent department of the State Council, promptly destroy pathogenic microorganism strains (viruses) and samples on site or submit them to preservation institutions for custody.

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Preservation institutions accepting pathogenic microorganism strains (viruses) and samples submitted by laboratories shall register them and issue a receipt certificate.

Article 17 — Where highly pathogenic microorganism strains (viruses) or samples are stolen, robbed, lost or leaked during transport or storage, the carrier, the escorting personnel and the preservation institution shall take necessary control measures and, within two hours, respectively report to the competent department of the carrier, the unit of the escorting personnel and the competent department of the preservation institution, and simultaneously report to the health competent department or the veterinary competent department of the people's government at the county level at the place where the incident occurred; where theft, robbery or loss occurs, they shall also report to the public security organ. The health competent department or the veterinary competent department receiving the report shall report to the people's government at the corresponding level within two hours, and simultaneously report to the health competent department or the veterinary competent department of the people's government at the higher level and the health competent department or the veterinary competent department of the State Council.

The people's government at the county level shall report to the people's government of the city divided into districts or the people's government at the next higher level within two hours after receiving the report; the people's government of the city divided into districts shall report to the people's government of the province, autonomous region or municipality directly under the Central Government within two hours after receiving the report. The people's government of the province, autonomous region or municipality directly under the Central Government shall report to the health competent department or the veterinary competent department of the State Council within one hour after receiving the report.

Where any unit or individual discovers containers or packaging materials of highly pathogenic microorganism strains (viruses) or samples, it shall promptly report to the nearby health competent department or veterinary competent department; the health competent department or veterinary competent department receiving the report shall promptly organize investigation and verification and take necessary control measures in accordance with the law.

Chapter III — Establishment and Administration of Laboratories

Article 18 — The State classifies laboratories into BSL-1, BSL-2, BSL-3 and BSL-4 according to the biosafety protection level of laboratories against pathogenic microorganisms and in accordance with the provisions of the national standards for laboratory biosafety.

Article 19 — The construction, reconstruction or expansion of BSL-3 or BSL-4 laboratories, or the production or import of mobile BSL-3 or BSL-4 laboratories, shall comply with the following provisions:

(1) conforming to the national biosafety laboratory system plan and completing the relevant examination and approval procedures in accordance with the law;

(2) having been reviewed and approved by the health competent department of the State Council;

(3) conforming to the national technical specifications for biosafety laboratory construction;

(4) having undergone ecological environment impact assessment in accordance with the law; and

(5) having a biosafety protection level commensurate with the experimental activities intended to be conducted.

The national biosafety laboratory system plan referred to in the preceding paragraph shall be formulated by the investment competent department of the State Council in conjunction with the relevant departments of the State Council. The formulation of the national biosafety laboratory system plan shall follow the principles of total quantity control, rational layout and resource sharing, and shall convene hearings or demonstration meetings to hear the opinions of experts in public health, environmental protection, investment administration and laboratory administration.

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Article 20 — BSL-3 and BSL-4 laboratories shall pass national laboratory accreditation.

The accreditation institution determined by the certification and accreditation supervision and administration department of the State Council shall accredit BSL-3 and BSL-4 laboratories in accordance with the national standards for laboratory biosafety and the relevant provisions of these Regulations; where a laboratory passes accreditation, a biosafety laboratory certificate of the corresponding level shall be issued. The validity period of the certificate is five years.

Article 21 — Experimental activities involving pathogenic microorganisms shall be conducted in laboratories of the corresponding level. The level of a laboratory conducting experimental activities involving pathogenic microorganisms shall be no lower than the laboratory level required for such experimental activities as prescribed in the catalogue of pathogenic microorganisms.

BSL-1 and BSL-2 laboratories may only conduct highly pathogenic microorganism experimental activities that the catalogue of pathogenic microorganisms permits to be conducted in BSL-1 and BSL-2 laboratories. BSL-3 and BSL-4 laboratories conducting highly pathogenic microorganism experimental activities shall meet the following conditions:

(1) the experimental purpose and the intended experimental activities conform to the provisions of the health competent department or the veterinary competent department of the State Council;

(2) having passed national laboratory accreditation;

(3) having staff members commensurate with the intended experimental activities; and

(4) the project quality has passed inspection and acceptance by the construction competent department in accordance with the law.

Article 22 — Where BSL-3 or BSL-4 laboratories need to conduct highly pathogenic microorganism experimental activities or suspected highly pathogenic microorganism experimental activities that the catalogue of pathogenic microorganisms prescribes shall be conducted in BSL-3 or BSL-4 laboratories, they shall report to the health competent department or the veterinary competent department of the people's government at or above the provincial level for approval in accordance with the provisions of the health competent department or the veterinary competent department of the State Council. The results of the experimental activities and the work situation shall be reported to the original approving department.

Laboratories applying for or undertaking scientific research projects related to highly pathogenic microorganisms shall conform to scientific research needs and biosafety requirements and have the corresponding biosafety protection level. Scientific research projects related to highly pathogenic microorganisms transmissible between animals shall be subject to the consent of the veterinary competent department of the State Council; for scientific research projects related to highly pathogenic microorganisms concerning human health, the laboratory shall inform the health competent department of the people's government at or above the provincial level of the project approval results.

Article 23 — Where entry-exit inspection and quarantine institutions, medical and health institutions, and animal disease prevention and control institutions discover highly pathogenic microorganisms or suspected highly pathogenic microorganisms during testing and diagnostic work in laboratories, and need to further conduct experimental activities related to such highly pathogenic microorganisms, they shall do so in laboratories meeting the corresponding conditions; where approval is required in accordance with these Regulations, approval shall be obtained.

Laboratories specializing in testing and diagnosis shall strictly comply with the provisions of the health competent department or the veterinary competent department of the State Council, and establish and improve rules and regulations to ensure laboratory biosafety.

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Article 24 — The health competent department or the veterinary competent department of the people's government at or above the provincial level shall, within 15 days from the date of receipt of an application to conduct highly pathogenic microorganism-related experimental activities, make a decision on whether to approve.

Where an entry-exit inspection and quarantine institution applies, due to urgent inspection and quarantine needs, to conduct further experimental activities on highly pathogenic microorganisms or suspected highly pathogenic microorganisms in a laboratory, the health competent department or the veterinary competent department of the people's government at or above the provincial level shall make a decision on whether to approve within two hours from the time of receipt of the application; where no decision is made within two hours, the laboratory may conduct the corresponding experimental activities.

The health competent department or the veterinary competent department of the people's government at or above the provincial level shall provide convenience for applicants to submit applications by telegraph, telex, facsimile, electronic data interchange, e-mail and other means.

Article 25 — The construction, reconstruction or expansion of BSL-1 or BSL-2 laboratories shall be filed with the health competent department or the veterinary competent department of the people's government of a city divided into districts. The health competent department or the veterinary competent department of the people's government of the city divided into districts shall annually summarize the filing information and report it to the health competent department or the veterinary competent department of the people's government of the province, autonomous region or municipality directly under the Central Government.

Article 26 — The health competent department and the veterinary competent department of the State Council shall regularly summarize and mutually notify the number of laboratories, the establishment and distribution of laboratories, and the situation of highly pathogenic microorganism experimental activities conducted by BSL-3 and BSL-4 laboratories.

Article 27 — BSL-3 and BSL-4 laboratories that have been completed and have passed national laboratory accreditation shall file with the environmental protection competent department of the people's government at the county level at their location. The environmental protection competent department shall, in accordance with the provisions of laws and administrative regulations, supervise and inspect the disposal of wastewater, waste gas and other waste discharged by laboratories.

Article 28 — No unit or individual may, without approval, conduct experimental activities related to pathogenic microorganisms that China has not yet discovered or has declared eradicated.

Where, for the prevention and control of infectious diseases, it is necessary to conduct experimental activities related to the pathogenic microorganisms referred to in the preceding paragraph, approval shall be obtained from the health competent department or the veterinary competent department of the State Council, and the activities shall be conducted in specialized laboratories designated by the approving department.

Article 29 — Where a laboratory uses new technologies or new methods to conduct highly pathogenic microorganism-related experimental activities, it shall conform to the requirements of preventing the spread of highly pathogenic microorganisms and ensuring biosafety and the personal safety of operators, and shall be subject to demonstration by the National Expert Committee on Pathogenic Microorganism Laboratory Biosafety; such technologies or methods may be used only after demonstration of feasibility.

Article 30 — Where highly pathogenic microorganism-related experimental activities need to be conducted on animals, they shall be conducted in laboratories of the corresponding level that conform to the national standards for animal laboratory biosafety, in accordance with the provisions of the catalogue of pathogenic microorganisms.

Article 31 — The unit establishing a laboratory is responsible for the biosafety administration of the laboratory.

The unit establishing a laboratory shall formulate scientific and strict administrative systems in accordance with these Regulations, regularly inspect the implementation of the relevant biosafety provisions, and regularly inspect, maintain and update laboratory facilities, equipment and materials to ensure that they conform to national standards.

The unit establishing a laboratory and its competent department shall strengthen the administration of the routine activities of the laboratory.

Article 32 — The person in charge of a laboratory is the first person responsible for laboratory biosafety.

Laboratories conducting experimental activities shall strictly comply with the relevant national standards and laboratory technical specifications and operating procedures. The person in charge of a laboratory shall designate dedicated personnel to supervise and inspect the implementation of laboratory technical specifications and operating procedures.

Article 33 — The unit establishing a laboratory conducting highly pathogenic microorganism-related experimental activities shall establish and improve security systems, take security measures, strictly prevent highly pathogenic microorganisms from being stolen, robbed, lost or leaked, and ensure the safety of the laboratory and its pathogenic microorganisms. Where highly pathogenic microorganisms are stolen, robbed, lost or leaked from a laboratory, the unit establishing the laboratory shall report in accordance with Article 17 of these Regulations.

Laboratories conducting highly pathogenic microorganism-related experimental activities shall file with the local public security organ and accept the supervision and guidance of the public security organ on laboratory security work.

Article 34 — A laboratory or the unit establishing it shall train its staff members on a regular annual basis, ensuring that they master laboratory technical specifications, operating procedures, biosafety protection knowledge and practical operational skills, and shall conduct assessments. Staff members may commence work only after passing assessment.

Laboratories conducting highly pathogenic microorganism-related experimental activities shall report the training and assessment of their staff members and the operation of the laboratory to the health competent department or the veterinary competent department of the people's government of the province, autonomous region or municipality directly under the Central Government every six months.

Article 35 — Highly pathogenic microorganism-related experimental activities shall be conducted jointly by no fewer than two staff members.

Staff members or other relevant personnel entering laboratories conducting highly pathogenic microorganism-related experimental activities shall be subject to the approval of the person in charge of the laboratory. The laboratory shall provide them with protective articles conforming to the protection requirements and take other occupational protection measures. Laboratories conducting highly pathogenic microorganism-related experimental activities shall also conduct health monitoring of laboratory staff members, organize annual physical examinations for them, and establish health archives; where necessary, preventive vaccination shall be administered to laboratory staff members.

Article 36 — Within the same independent safety area of the same laboratory, experimental activities related to only one type of highly pathogenic microorganism may be conducted simultaneously.

Article 37 — Laboratories shall establish experimental archives, recording laboratory use and safety supervision. The retention period of experimental archives for laboratories conducting highly pathogenic microorganism-related experimental activities shall be no less than 20 years.

Article 38 — Laboratories shall dispose of wastewater, waste gas and other waste in accordance with the relevant environmental protection laws, administrative regulations and the provisions of the relevant

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departments of the State Council, and formulate corresponding environmental protection measures to prevent environmental pollution.

Article 39 — BSL-3 and BSL-4 laboratories shall conspicuously display the biohazard markings and the biosafety laboratory level markings prescribed by the health competent department and the veterinary competent department of the State Council.

Article 40 — Laboratories conducting highly pathogenic microorganism-related experimental activities shall formulate emergency response plans for laboratory biosafety incidents and file them with the health competent department or the veterinary competent department of the people's government of the province, autonomous region or municipality directly under the Central Government at the laboratory's location.

Article 41 — The health competent department and the veterinary competent department of the State Council shall, in conjunction with the relevant departments of the State Council, organize experts in etiology, immunology, laboratory medicine, epidemiology, preventive veterinary medicine, environmental protection and laboratory administration to form the National Expert Committee on Pathogenic Microorganism Laboratory Biosafety. The Committee undertakes biosafety assessment, technical consultation and demonstration work for the establishment and operation of laboratories conducting highly pathogenic microorganism-related experimental activities.

The health competent department and the veterinary competent department of the people's government of a province, autonomous region or municipality directly under the Central Government shall, in conjunction with the relevant departments of the people's government at the same level, organize experts in etiology, immunology, laboratory medicine, epidemiology, preventive veterinary medicine, environmental protection and laboratory administration to form the regional Expert Committee on Pathogenic Microorganism Laboratory Biosafety. The Committee undertakes technical consultation work for the establishment and operation of laboratories in the region.

Chapter IV — Control of Laboratory Infections

Article 42 — The unit establishing a laboratory shall designate a specialized institution or personnel to undertake laboratory infection control work, and regularly inspect the implementation of rules and regulations concerning laboratory biosafety protection, the preservation and use of pathogenic microorganism strains (viruses) and samples, safe operation, and the disposal of wastewater, waste gas and other waste discharged by the laboratory.

The institution or personnel responsible for laboratory infection control work shall possess knowledge of the prevention and treatment of infectious diseases related to the pathogenic microorganisms in the laboratory, and shall regularly investigate and understand the health status of laboratory staff members.

Article 43 — Where a laboratory staff member develops clinical symptoms or signs of infection related to the highly pathogenic microorganism experimental activities conducted by the laboratory, the person in charge of the laboratory shall report to the institution or personnel responsible for laboratory infection control work, and simultaneously arrange dedicated personnel to accompany the staff member for timely medical treatment; the laboratory staff member shall truthfully inform the treating medical institution of the types and degree of danger of the pathogenic microorganisms recently contacted. The medical institution receiving the patient shall provide timely treatment; where it does not have the corresponding treatment conditions, it shall transfer the infected laboratory staff member to a medical institution with the corresponding conditions for treating infectious diseases in accordance with the provisions; the medical institution with the corresponding conditions shall admit and treat the patient and shall not refuse treatment.

Article 44 — Where a laboratory has a leak of highly pathogenic microorganisms, laboratory staff members shall immediately take control measures to prevent the spread of highly pathogenic microorganisms, and simultaneously report to the institution or personnel responsible for laboratory infection control work.

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Article 45 — The institution or personnel responsible for laboratory infection control work shall, after receiving the reports prescribed in Articles 43 and 44 of these Regulations, immediately activate the laboratory biosafety incident emergency response plan and organize personnel to investigate the laboratory biosafety situation; where a laboratory infection or a leak of highly pathogenic microorganisms is confirmed, it shall report in accordance with Article 17 of these Regulations, and simultaneously take control measures, conduct medical observation or isolated treatment of the relevant personnel, and seal the laboratory to prevent spread.

Article 46 — Where the health competent department or the veterinary competent department receives a report on a staff member infection accident or a pathogenic microorganism leak incident in a laboratory, or discovers that laboratory infection accidents have been caused by laboratory pathogenic microorganism-related experimental activities, it shall immediately organize disease prevention and control institutions, animal disease prevention and control institutions, medical institutions and other relevant institutions to take the following preventive and control measures in accordance with the law:

(1) sealing laboratories contaminated by pathogenic microorganisms or premises that may cause the spread of pathogenic microorganisms;

(2) carrying out epidemiological investigation;

(3) carrying out isolated treatment of patients and medical examination of relevant personnel;

(4) carrying out medical observation of close contacts;

(5) carrying out on-site disinfection;

(6) taking isolation, culling and other measures for infected or suspected infected animals; and

(7) other preventive and control measures that need to be taken.

Article 47 — Where a medical institution or a veterinary medical institution or its medical personnel on duty discovers an infectious disease patient, suspected infectious disease patient, or an animal suffering from or suspected of suffering from an epidemic disease related to highly pathogenic microorganisms caused by laboratory infection, the treating medical institution or veterinary medical institution shall report to the health competent department or the veterinary competent department of the people's government at the county level at its location within two hours; the health competent department or the veterinary competent department receiving the report shall notify the health competent department or the veterinary competent department of the people's government at the county level at the laboratory's location within two hours. The health competent department or the veterinary competent department receiving the notification shall take preventive and control measures in accordance with Article 46 of these Regulations.

Article 48 — Where the spread of pathogenic microorganisms occurs and may cause an outbreak or epidemic of an infectious disease, the health competent department or the veterinary competent department of the people's government at or above the county level shall handle it in accordance with the relevant laws and administrative regulations and the laboratory biosafety incident emergency response plan.

Chapter V — Supervision and Administration

Article 49 — The health competent departments and veterinary competent departments of local people's governments at or above the county level shall, according to their respective division of work, perform the following duties:

(1) supervising and inspecting the collection, transport and storage of pathogenic microorganism strains (viruses) and samples;

(2) supervising and inspecting whether laboratories conducting highly pathogenic microorganism-related experimental activities conform to the conditions prescribed in these Regulations;

(3) supervising and inspecting the training and assessment of staff members and the commencement of work by on-duty personnel by laboratories or the units establishing them; and

(4) supervising and inspecting whether laboratories conduct pathogenic microorganism-related experimental activities in accordance with the relevant national standards, technical specifications and operating procedures.

The health competent departments and veterinary competent departments of local people's governments at or above the county level shall effectively perform their supervision and administration duties mainly by inspecting the records, archives and reports reflecting laboratories' implementation of the relevant national laws, administrative regulations, national standards and requirements.

Article 50 — When performing supervision and inspection duties, the health competent departments, veterinary competent departments and environmental protection competent departments of people's governments at or above the county level shall have the right to enter the inspected units and the sites of pathogenic microorganism leaks or spread to investigate, collect evidence and take samples, and to consult and copy relevant materials. Where it is necessary to enter laboratories conducting highly pathogenic microorganism-related experimental activities to investigate, collect evidence and take samples, specialized institutions shall be designated or commissioned to do so. The inspected units shall cooperate and shall not refuse or obstruct.

Article 51 — The certification and accreditation supervision and administration department of the State Council shall supervise and inspect laboratory accreditation activities in accordance with the provisions of the Regulations of the People's Republic of China on Certification and Accreditation.

Article 52 — The health competent departments, veterinary competent departments and environmental protection competent departments shall perform their duties in accordance with their statutory powers and procedures, and act with justice, fairness, openness, civility and efficiency.

Article 53 — When performing their duties, law enforcement personnel of the health competent departments, veterinary competent departments and environmental protection competent departments shall be no fewer than two in number, present their law enforcement certificates, and complete law enforcement documents in accordance with the provisions.

On-site inspection records, sampling records and other documents shall, after verification, be signed by the law enforcement personnel and the inspected or sampled persons. Where the inspected or sampled persons refuse to sign, the law enforcement personnel shall note the circumstances after signing themselves.

Article 54 — The health competent departments, veterinary competent departments and environmental protection competent departments and their law enforcement personnel shall, when performing their duties, consciously accept supervision by society and citizens. Citizens, legal persons and other organizations have the right to report to the people's government at a higher level and its health competent department, veterinary competent department or environmental protection competent department the failure of a local people's government and its relevant competent departments to perform their duties in accordance with the provisions. The relevant people's government or its health competent department, veterinary competent department or environmental protection competent department receiving the report shall promptly investigate and handle it.

Article 55 — Where the health competent department, veterinary competent department or environmental protection competent department of a people's government at a higher level discovers matters that need to be handled within the scope of duties of the health competent department, veterinary competent department or environmental protection competent department of a people's government at a lower level, it shall promptly inform such department to handle them; where the health competent department, veterinary competent department or environmental protection competent department of the people's government at the

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lower level fails to handle them in a timely manner or fails to actively perform its duties, the health competent department, veterinary competent department or environmental protection competent department of the people's government at the higher level shall order it to rectify within a prescribed time limit; where rectification is not made within the time limit, the higher-level department shall have the right to handle the matter directly.

Chapter VI — Legal Liability

Article 56 — Where a BSL-3 or BSL-4 laboratory conducts, without approval, highly pathogenic microorganism experimental activities or suspected highly pathogenic microorganism experimental activities that the catalogue of pathogenic microorganisms prescribes shall be conducted in BSL-3 or BSL-4 laboratories, the health competent department or the veterinary competent department of the local people's government at or above the county level shall, according to their respective duties, order cessation of the relevant activities, supervise the destruction or submission to preservation institutions of the pathogenic microorganisms used for the experimental activities, and give a warning; where the spread or epidemic of an infectious disease or other serious consequences are caused, the unit establishing the laboratory shall impose sanctions of removal from office or expulsion on the principal person in charge, the directly responsible person in charge and other directly responsible personnel in accordance with the law; where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Article 57 — Where the health competent department or the veterinary competent department, in violation of these Regulations, approves a laboratory that does not conform to the conditions prescribed in these Regulations to conduct highly pathogenic microorganism-related experimental activities, the health competent department or the veterinary competent department that made the approval decision shall revoke the original approval decision, order the relevant laboratory to immediately cease the relevant activities, supervise the destruction or submission to preservation institutions of the pathogenic microorganisms used for the experimental activities, and impose administrative sanctions on the directly responsible person in charge and other directly responsible personnel in accordance with the law; where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Where damage is caused to the lawful rights and interests of a party by an illegally made approval decision, the health competent department or the veterinary competent department that made the approval decision shall bear liability for compensation in accordance with the law.

Article 58 — Where the health competent department or the veterinary competent department fails to make a decision on whether to approve within the statutory time limit in respect of an application by an entry-exit inspection and quarantine institution, due to urgent inspection and quarantine needs, to conduct further testing activities on highly pathogenic microorganisms or suspected highly pathogenic microorganisms in a laboratory, the administrative organ at a higher level or the supervisory authority shall order correction and give a warning; where the spread or epidemic of an infectious disease or other serious consequences are caused, administrative sanctions of removal from office or expulsion shall be imposed on the directly responsible person in charge and other directly responsible personnel in accordance with the law; where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Article 59 — Where, in violation of these Regulations, pathogenic microorganism-related experimental activities are conducted in a laboratory that does not meet the corresponding biosafety requirements, the health competent department or the veterinary competent department of the local people's government at or above the county level shall, according to their respective duties, order cessation of the relevant activities, supervise the destruction or submission to preservation institutions of the pathogenic microorganisms used for the experimental activities, and give a warning; where the spread or epidemic of an infectious disease or other serious consequences are caused, the unit establishing the laboratory shall impose sanctions of removal from office or expulsion on the principal person in charge, the directly responsible person in charge

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and other directly responsible personnel in accordance with the law; where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Article 60 — Where a laboratory commits any of the following acts, the health competent department or the veterinary competent department of the local people's government at or above the county level shall, according to their respective duties, order rectification within a prescribed time limit and give a warning; where rectification is not made within the time limit, the unit establishing the laboratory shall impose sanctions of removal from office or expulsion on the principal person in charge, the directly responsible person in charge and other directly responsible personnel in accordance with the law; where there are license documents, the original license-issuing department shall also revoke the relevant license documents:

(1) failing to conspicuously display the biohazard markings and the biosafety laboratory level markings prescribed by the health competent department and the veterinary competent department of the State Council;

(2) failing to report the results of experimental activities and the work situation to the original approving department;

(3) failing to collect pathogenic microorganism samples in accordance with the provisions, or failing to make detailed records of the source, collection process and methods of the collected samples;

(4) failing to file the construction, reconstruction or expansion of a BSL-1 or BSL-2 laboratory with the health competent department or the veterinary competent department of the people's government of a city divided into districts;

(5) failing to regularly train staff members in accordance with the provisions, or allowing staff members who have failed assessment to commence work, or approving personnel who have not taken protective measures to enter the laboratory;

(6) laboratory staff members failing to comply with laboratory biosafety technical specifications and operating procedures;

(7) failing to establish or preserve experimental archives in accordance with the provisions; or

(8) failing to formulate and file a laboratory biosafety incident emergency response plan in accordance with the provisions.

Article 61 — Where the unit establishing a laboratory conducting highly pathogenic microorganism-related experimental activities fails to establish and improve security systems or fails to take security measures, the health competent department or the veterinary competent department of the local people's government at or above the county level shall, according to their respective duties, order rectification within a prescribed time limit; where rectification is not made within the time limit and highly pathogenic microorganism strains (viruses) or samples are stolen or robbed or other serious consequences are caused, the experimental activity shall be ordered to cease, and the laboratory shall not conduct highly pathogenic microorganism experimental activities within two years; where the spread or epidemic of an infectious disease is caused, the competent department of the unit establishing the laboratory shall also impose sanctions of demotion, removal from office or expulsion on the directly responsible person in charge and other directly responsible personnel of the unit establishing the laboratory in accordance with the law; where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Article 62 — Where highly pathogenic microorganism strains (viruses) or samples are transported without approval, or a carrier transporting approved highly pathogenic microorganism strains (viruses) or samples fails to perform its protection obligations, resulting in the theft, robbery, loss or leakage of the highly pathogenic microorganism strains (viruses) or samples, the health competent department or the veterinary competent department of the local people's government at or above the county level shall, according to their respective duties, order the taking of measures to eliminate hazards and give a warning; where the spread or

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epidemic of an infectious disease or other serious consequences are caused, the competent departments of the consignor and the carrier shall impose sanctions of removal from office or expulsion on the principal person in charge, the directly responsible person in charge and other directly responsible personnel in accordance with the law; where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Article 63 — Where any of the following acts is committed, the health competent department or the veterinary competent department of the local people's government at or above the level of a city divided into districts at the laboratory's location shall, according to their respective duties, order the relevant unit to immediately cease the illegal activity and supervise the destruction or submission to preservation institutions of the pathogenic microorganisms; where the spread or epidemic of an infectious disease or other serious consequences are caused, the unit or its competent department at a higher level shall impose sanctions of removal from office or expulsion on the principal person in charge, the directly responsible person in charge and other directly responsible personnel in accordance with the law; where there are license documents, the original license-issuing department shall also revoke the relevant license documents; where a crime is constituted, criminal liability shall be pursued in accordance with the law:

(1) a laboratory failing, after the completion of relevant experimental activities, to promptly destroy pathogenic microorganism strains (viruses) and samples on site or submit them to preservation institutions for custody in accordance with the provisions;

(2) a laboratory using new technologies or new methods to conduct highly pathogenic microorganism-related experimental activities without demonstration by the National Expert Committee on Pathogenic Microorganism Laboratory Biosafety;

(3) conducting, without approval, experimental activities related to pathogenic microorganisms that China has not yet discovered or has declared eradicated;

(4) conducting experimental activities related to pathogenic microorganisms that China has not yet discovered or has declared eradicated in specialized laboratories not designated for such activities; or

(5) simultaneously conducting experimental activities related to two or more types of highly pathogenic microorganisms within the same independent safety area of the same laboratory.

Article 64 — Where an accreditation institution accredits a laboratory that does not conform to the national standards for laboratory biosafety and the conditions prescribed in these Regulations, or refuses to accredit a laboratory that conforms to the national standards for laboratory biosafety and the conditions prescribed in these Regulations, the certification and accreditation supervision and administration department of the State Council shall order rectification within a prescribed time limit and give a warning; where the spread or epidemic of an infectious disease or other serious consequences are caused, the certification and accreditation supervision and administration department of the State Council shall revoke its accreditation qualification; where there is a competent department at a higher level, such department shall impose sanctions of removal from office or expulsion on the principal person in charge, the directly responsible person in charge and other directly responsible personnel in accordance with the law; where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Article 65 — Where a laboratory staff member develops clinical symptoms or signs of infection related to the pathogenic microorganism experimental activities conducted by the laboratory, or where a laboratory has a leak of highly pathogenic microorganisms, and the person in charge of the laboratory, laboratory staff members, or the specialized institution or personnel responsible for laboratory infection control fail to report in accordance with the provisions or fail to take control measures in accordance with the provisions, the health competent department or the veterinary competent department of the local people's government at or above the county level shall, according to their respective duties, order rectification within a prescribed time limit and give a warning; where the spread or epidemic of an infectious disease or other serious

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consequences are caused, the unit establishing the laboratory shall impose sanctions of removal from office or expulsion on the principal person in charge of the laboratory, the directly responsible person in charge and other directly responsible personnel in accordance with the law; where there are license documents, the original license-issuing department shall also revoke the relevant license documents; where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Article 66 — Where a party refuses to accept the lawful investigation, evidence collection and sampling activities concerning the spread of highly pathogenic microorganisms, or refuses to accept the relevant preventive and control measures taken in accordance with these Regulations, the health competent department or the veterinary competent department of the people's government at or above the county level shall, according to their respective duties, order correction and give a warning; where the spread or epidemic of an infectious disease or other serious consequences are caused, the unit establishing the laboratory shall impose sanctions of demotion, removal from office or expulsion on the principal person in charge of the laboratory, the directly responsible person in charge and other directly responsible personnel in accordance with the law; where there are license documents, the original license-issuing department shall also revoke the relevant license documents; where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Article 67 — Where pathogenic microorganisms are stolen, robbed, lost or leaked, and the carrier, escorting personnel, preservation institution or the unit establishing the laboratory fails to report in accordance with these Regulations, the health competent department or the veterinary competent department of the people's government at the county level at the place of the incident shall give a warning; where the spread or epidemic of an infectious disease or other serious consequences are caused, the competent department at a higher level of the unit establishing the laboratory, the carrier or the preservation institution shall impose sanctions of removal from office or expulsion on the principal person in charge, the directly responsible person in charge and other directly responsible personnel in accordance with the law; where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Article 68 — Where a preservation institution fails to store the strains (viruses) and samples submitted by laboratories in accordance with the provisions, or fails to provide strains (viruses) and samples in accordance with the provisions, the department designating it shall order rectification within a prescribed time limit, recover the illegally provided strains (viruses) and samples, and give a warning; where the spread or epidemic of an infectious disease or other serious consequences are caused, the unit or its competent department at a higher level shall impose sanctions of removal from office or expulsion on the principal person in charge, the directly responsible person in charge and other directly responsible personnel in accordance with the law; where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Article 69 — Where the relevant competent departments of people's governments at or above the county level fail to perform their supervision and inspection duties over laboratories and their experimental activities in accordance with these Regulations, the relevant people's government shall order correction and give a circular of criticism within the scope of its respective duties; where the spread or epidemic of an infectious disease or other serious consequences are caused, administrative sanctions shall be imposed on the directly responsible person in charge in accordance with the law; where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Chapter VII — Supplementary Provisions

Article 70 — Military laboratories shall be supervised and administered by the health competent department of the Chinese People's Liberation Army with reference to these Regulations.

Article 71 — Laboratories established before the implementation of these Regulations shall complete the relevant procedures in accordance with these Regulations within six months from the date of implementation

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of these Regulations.

Article 72 — These Regulations shall come into force as of the date of promulgation.

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