
Regulations on Administration of Biosafety in Pathogenic Microorganism Laboratories

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Chapter I General Principles

Article 1 These Regulations are formulated for the purposes of strengthening administration of the biosafety in pathogenic microorganism laboratories (hereinafter referred to as "laboratories") and protecting the health of laboratory staff and the public.

Article 2 These Regulations are applicable to administration of the biosafety in laboratories and of the laboratory activities conducted by such laboratories within the territory of the People's Republic of China.

The term "pathogenic microorganisms" in these Regulations means organisms that are pathogenic to human beings or animals.

The term "laboratory activities" in these Regulations means teaching, testing, diagnosis and other activities related to bacteria (virus) strains or samples of pathogenic microorganisms that are conducted by a laboratory.

Article 3 The competent health department of the State Council shall take charge of supervision of the biosafety in laboratories that are related to human health and the laboratory activities conducted by such laboratories.

The competent veterinary department of the State Council shall take charge of supervision of the biosafety in laboratories that are related to animals and the laboratory activities conducted by such laboratories.

Other relevant departments of the State Council shall, within the scope of their respective functions and duties, be responsible for administration of the biosafety in laboratories.

The local people's governments at or above the county level and their competent

departments shall, within the scope of their respective functions and duties, be responsible for administration of the biosafety in laboratories and the laboratory activities conducted by such laboratories.

Article 4 The State exercises classified administration of pathogenic microorganisms and level-based administration of laboratories.

Article 5 The State applies unified standards for biosafety in laboratories. Laboratories shall be in compliance with the standards and requirements of the State.

Article 6 The establisher of a laboratory and the competent department thereof shall supervise the daily activities of the laboratory, and fulfill the responsibilities of establishing and improving the safety management system, examining and maintaining the facilities and equipment, and preventing laboratory infection.

Chapter II Classification and Administration of Pathogenic Microorganisms

Article 7 On the basis of the infectivity of pathogenic microorganisms and their risk level to individuals or the community after infection, the State classifies pathogenic microorganisms into the following four Risk Groups:

Risk Group 1: pathogenic microorganisms that can cause very serious human or animal diseases, pathogenic microorganisms that have not been detected in the country, and pathogenic microorganisms that have been announced eradicated in the country.

Risk Group 2: pathogenic microorganisms that can cause serious human or animal diseases and that can be readily transmitted between human beings, human beings and animals, or animals directly or indirectly.

Risk Group 3: pathogenic microorganisms that can cause human or animal diseases but under normal circumstances, is unlikely to be a serious hazard to human beings, animals or the environment, that have only limited risk of spread, that rarely cause serious diseases in case of laboratory exposure, and for which the effective treatment and preventive measures are available.

Risk Group 4: pathogenic microorganisms that are unlikely to cause human or animal diseases under normal circumstances.

Risk Group 1 and Risk Group 2 are collectively referred to as “highly pathogenic microorganisms”.

Article 8 A catalogue of pathogenic microorganisms transmitting between human beings shall be formulated, adjusted and published by the competent health department of the State Council after consulting with the relevant departments of the State Council; and a catalogue of pathogenic microorganisms transmitting between animals shall be formulated, adjusted and published by the competent veterinary department of the State Council after consulting with the relevant departments of the State Council.

Article 9 Any unit that is to collect samples of pathogenic microorganisms shall meet the following requirements:

(1)having the equipment commensurate with the biosafety level necessary for the collection of samples of pathogenic microorganisms;

(2)having staff members with a mastery of relevant professional knowledge and operation skills;

(3)having measures for effective control of spread and infection of pathogenic microorganisms; and

(4)having technical methodology and measures to ensure the quality of samples of pathogenic microorganisms collected.

The staff members collecting samples of highly pathogenic microorganisms shall, during the collection, prevent the spread and infection of pathogenic microorganisms, and keep a detailed record of the source of the collected samples, the process of the collection, the methodology applied, and other information concerned.

Article 10 Bacteria (virus) strains or samples of highly pathogenic microorganisms shall be transported by land. Where there is no land route and only water routes are available, they may be transported by water. In case of emergency or where there is a need to transport them to a foreign country, they may be transported by means of civil aviation.

Article 11 The following requirements shall be met for transportation of bacteria (virus) strains or samples of highly pathogenic microorganisms:

(1) the purpose of transportation and the use and consignee of the highly pathogenic microorganisms transported shall be in compliance with the provisions set forth by the competent health department or the competent veterinary department of the State Council;

(2) the containers of bacteria (virus) strains or samples of highly pathogenic microorganisms shall be airtight. In addition, the containers and packaging materials thereof shall meet the requirements for waterproofing and resistance against breakage, leakage, temperature extremes and high pressure; and

(3) the containers and packaging materials of bacteria (virus) strains or samples of highly pathogenic microorganisms shall bear biohazard signs, warning signs and directions as required by the competent health department or the competent veterinary department of the State Council.

Transportation of bacteria (virus) strains or samples of highly pathogenic microorganisms shall be subject to the approval of the competent health department or the competent veterinary department of the people's government at or above the provincial level. If the bacteria (virus) strains or samples of highly pathogenic microorganisms are to be transported within a province, autonomous region or municipality directly under the Central Government, such transportation shall be subject to the approval of the competent health department or the competent veterinary department of people's government of the province, autonomous region or municipality directly under the Central Government in question; if such transportation is to go across two or more provinces, autonomous regions or municipalities directly under the Central Government or is to go out of the territory of the country, the matter shall be subject to the preliminary examination by the competent health department or the competent veterinary department of the people's government of the departing province, autonomous region or municipality directly under the Central Government, and then be submitted to the competent health department or the competent veterinary department of the State Council for approval.

Where an entry-exit inspection and quarantine institution needs to transport samples of pathogenic microorganisms in the process of inspection and quarantine, such transportation shall be subject to the approval of the entry-exit inspection and quarantine department of the State Council and notified to the competent health department or the competent veterinary department of the State Council at the same time.

For transportation of bacteria (virus) strains or samples of highly pathogenic microorganisms by civil aviation, the approval of the competent civil aviation department of the State Council shall be obtained in addition to the approval as required by the second and third paragraphs of this Article.

The relevant competent department shall examine the application submitted by the applicant for transportation of bacteria (virus) strains or samples of highly pathogenic microorganisms, and make a prompt approval if all the requirements specified in the first paragraph of this Article are met.

Article 12 Two or more escorts shall be assigned and corresponding protection measures shall be adopted for transportation of bacteria (virus) strains or samples of highly pathogenic microorganisms.

Any unit or individual concerned shall not transport bacteria (virus) strains or samples of pathogenic microorganisms through public trolley (bus) system or municipal railways.

Article 13 Where there is a need to transport bacteria (virus) strains or samples of pathogenic microorganisms by such means of public transportation as railway, highway or civil aviation, the carrier shall conduct the transportation on the strength of the approval document specified in Article 11 of these Regulations.

The carrier shall, jointly with the escorts, adopt measures to ensure the safety of the transported bacteria (virus) strains or samples of highly pathogenic microorganisms, and to prevent any theft, robbery, loss or leakage.

Article 14 The bacteria (virus) strain collection centers and specialized laboratories designated by the competent health department or the competent veterinary department of the State Council (hereinafter collectively referred to as

resource institutions) shall undertake the centralized storage of bacteria (virus) strains and samples of pathogenic microorganisms.

A resource institution shall, in accordance with the provisions set forth by the competent health department or the competent veterinary department of the State Council, store bacteria (virus) strains and samples of pathogenic microorganisms submitted by laboratories, and provide laboratories with bacteria (virus) strains and samples of pathogenic microorganisms.

A resource institution shall develop a strict safe storage system, keep a record of all incoming, outgoing and storage of bacteria (virus) strains and samples of pathogenic microorganisms, establish a filing system, and designate staff members specifically for this purpose. The specific room or cabinet shall be prepared for storage of bacteria (virus) strains and samples of highly pathogenic microorganisms.

A resource institution shall charge no fees for the storage and provision of bacteria (virus) strains and samples of pathogenic microorganisms, and its funds shall be guaranteed by the finance department at the same level through budgetary appropriation.

The measures for administration of resource institutions shall be formulated by the competent health department of the State Council jointly with the competent veterinary department of the State Council.

Article 15 A resource institution shall, on the basis of the approval document obtained by a laboratory in accordance with these Regulations for conducting laboratory activities related to highly pathogenic microorganism, provide the laboratory with bacteria (virus) strains or samples of highly pathogenic microorganisms, and register the provision.

Article 16 Upon the conclusion of relevant laboratory activities, the laboratory in question shall, as required by the competent health department or the competent veterinary department of the State Council, promptly destroy the bacteria (virus) strains or samples of pathogenic microorganisms on the spot, or transfer them to a resource institution for storage.

A resource institution shall, upon receipt of the bacteria (virus) or samples of

pathogenic microorganisms transferred from the laboratory, register the receipt and issue a certificate of receipt.

Article 17 Where bacteria (virus) strains or samples of highly pathogenic microorganisms are stolen, robbed, lost or leaked in transportation or storage, the carrier, escorts or resource institution in question shall take necessary control measures, and, within two hours, report the matter respectively to the competent department of the carrier, the unit that the escorts belong to, and the competent department of the resource institution, and, at the same time, to the competent health department or the competent veterinary department of local people's government at the county level. In case of theft, robbery or loss, a report thereon shall also be made to the public security organ. Upon receipt of the report, the competent health department or the competent veterinary department shall, within two hours, report the matter to the people's government at the same level, the competent health department or the competent veterinary department of the people's government at a higher level, and the competent health department or the competent veterinary department of the State Council.

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

Upon finding containers or packing materials of bacteria (virus) strains or samples of highly pathogenic microorganisms, any unit or individual shall promptly report the matter to the competent health department or the competent veterinary department nearby. Upon receipt of such report, the competent health department or

the competent veterinary department shall promptly initiate an investigation for verification, and take necessary control measures according to law.

Chapter III Establishment and Administration of Laboratories

Article 18 On the basis of risk assessment of laboratories and in accordance with the standards of the State for laboratory biosafety, the State classifies laboratories into four Biosafety Levels, namely, Biosafety Level 1, Biosafety Level 2, Biosafety Level 3 and Biosafety Level 4.

Article 19 A project such as the construction, alteration or extension of a laboratory of Biosafety level 3 or Biosafety Level 4, or the production or import of a mobile laboratory of Biosafety Level 3 or Biosafety Level 4 shall be conducted in accordance with the following provisions:

(1)it shall conform to the State planning for the biosafety laboratory network, and the relevant formalities for examination and approval shall be gone through according to law;

(2)it shall be subject to the examination and approval by the competent science and technology department of the State Council;

(3)it shall conform to the technical standards of the State for construction of biosafety laboratories;

(4)its impact on the environment shall be assessed in accordance with the Law of the People's Republic of China on Environment Impact Assessment, and it shall be subject to the examination and approval by the competent environmental protection department; and

(5)its Biosafety Level shall be commensurate with the laboratory activities to be conducted therein.

The State planning for the biosafety laboratory network referred to in the preceding paragraph shall be formulated by the competent investment department of the State Council jointly with the relevant departments of the State Council. In the formulation of the State planning for the biosafety laboratory network, the principles

of aggregate control, rational distribution, and resources sharing shall be followed, and hearings or deliberation meetings shall be convened to solicit comments from experts of public health, environmental protection, investment management, and laboratory management, etc.

Article 20 Laboratories of Biosafety Level 3 and Biosafety Level 4 shall be accredited by the State.

The accreditation body designated by the certification and accreditation regulatory department of the State Council shall conduct accreditation of laboratories of Biosafety Level 3 and Biosafety Level 4 in accordance with the standards of the State for laboratory biosafety and the relevant provisions of these Regulations. Once accredited, a laboratory shall be issued a certificate of biosafety laboratory, the period of validity of which shall be five years.

Article 21 A Laboratory of Biosafety Level 1 or Biosafety Level 2 shall not conduct laboratory activities related to highly pathogenic microorganisms. A laboratory of Biosafety Level 3 or Biosafety Level 4 that is to conduct laboratory activities related to highly pathogenic microorganisms shall meet the following conditions:

(1) the purpose of the experiment and the laboratory activities to be conducted shall be in compliance with the provisions set forth by the competent health department or the competent veterinary department of the State Council;

(2) it has been accredited by the State;

(3) it has staff members commensurate with the laboratory activities to be conducted therein; and

(4) it has passed the acceptance test in terms of construction quality by the competent construction department according to law.

The competent health department or the competent veterinary department of the State Council shall, in accordance with its functions and duties, examine laboratories of Biosafety Level 3 and Biosafety Level 4 in terms of their compliance with the above-mentioned conditions, and issue to qualified laboratories qualification certificates for conducting laboratory activities related to highly pathogenic

microorganisms.

Article 22 Where a laboratory that has obtained a qualification certificate for conducting laboratory activities related to highly pathogenic microorganisms is to conduct laboratory activities related to certain highly pathogenic microorganisms or suspected highly pathogenic microorganisms, the laboratory shall, in accordance with the provisions of the competent health department or the competent veterinary department of the State Council, apply to the competent health department or the competent veterinary department of the people's government at or above the provincial level for approval. The results and other information on the laboratory activities shall be reported to the original approving department.

A laboratory that applies for or accepts a scientific research project related to highly pathogenic microorganisms shall conform to the needs for scientific research and the biosafety requirements, reach the appropriate Biosafety Level, and obtain the consent of the competent health department or the competent veterinary department of the State Council.

Article 23 Where an entry-exit inspection and quarantine institution, a medical or health institution, or an animal epidemic prevention institution detects highly pathogenic microorganisms or suspected highly pathogenic microorganisms in laboratory testing or diagnosis activities and there is a need to conduct further laboratory activities on the highly pathogenic microorganisms detected, the institution in question shall obtain the approval therefor in accordance with these Regulations and conduct the laboratory activities in a laboratory with the appropriate qualification certificate.

A laboratory specifically for testing and diagnosis shall, in strict compliance with the provisions of the competent health department or the competent veterinary department of the State Council, establish and improve the relevant bylaws to ensure laboratory biosafety.

Article 24 The competent health department or the competent veterinary department of the people's government at or above the provincial level shall, within 15 days from the date of receipt of the application for conducting laboratory activities

related to highly pathogenic microorganism, make a decision whether or not to grant the approval.

Where an entry-exit inspection and quarantine institution applies to conduct further laboratory activities on the highly pathogenic microorganisms or suspected highly pathogenic microorganisms in a laboratory to address the urgent need in its work, the competent health department or the competent veterinary department of the people's government at or above the provincial level shall, within two hours from receipt of the application, make a decision whether or not to grant the approval. If no decision is made within two hours, the laboratory in question may initiate the proposed laboratory activities.

The competent health department or the competent veterinary department of the people's government at or above the provincial level shall make it convenient for applicant to submit the application through telegram, telex, facsimile, electronic data exchange, or e-mail, etc.

Article 25 A project such as the construction, alteration or extension of a laboratory of Biosafety Level 3 or Biosafety Level 4 shall be reported for the record to the competent health department or the competent veterinary department of the people's government at the level of a city divided into districts, which shall conduct an annual consolidation thereof and make a report thereon to the competent health department or the competent veterinary department of the people's government of the province, autonomous region, municipality directly under the Central Government.

Article 26 The competent health department and veterinary department of the State Council shall collect and notify each other of the number of laboratories, the information on the establishment and distribution of laboratories, the information on laboratories of Biosafety Level 3 and Biosafety Level 4 with a qualification certificate for conducting laboratory activities related to highly pathogenic microorganisms, and the information on the laboratory activities that they conducted.

Article 27 A laboratory of Biosafety Level 3 or Biosafety Level 4 that has been constructed and that has been accredited by the State shall report for the record to the competent environmental protection department of the people's government at the

county level of the place where the laboratory in question is located, which shall, in accordance with the laws and administrative regulations, supervise and inspect the laboratory in terms of its disposal of waste water, waste gas or other waste discharged.

Article 28 No unit or individual may conduct, without approval, laboratory activities related to pathogenic microorganisms that have not been detected in the country or pathogenic microorganisms that has been announced eradicated in the country.

Where there is a need to conduct the laboratory activities related to pathogenic microorganisms referred to in the preceding paragraph for prevention and control of infectious diseases, the laboratory activities in question shall be subject to the approval of the competent health department or the competent veterinary department of the State Council, and be conducted in a laboratory designated by the approving department.

Article 29 The new technology or new methodology applied by a laboratory in its laboratory activities related to highly pathogenic microorganisms shall conform to the requirements for preventing the spread of highly pathogenic microorganisms and ensuring biosafety and the personal safety of the operators, and pass the deliberation of the State Experts' Committee on Biosafety of Pathogenic Microorganism Laboratories. Only those that have passed the deliberation may be applied.

Article 30 Where there is a need to conduct laboratory activities related to highly pathogenic microorganisms on animals, the laboratory activities in question shall be conducted by a laboratory at or above the Biosafety Level 3 that conforms to the State standards for biosafety of animal laboratories.

Article 31 The establisher of a laboratory shall be responsible for the biosafety administration of the laboratory established.

The establisher of a laboratory shall develop a scientific and strict management system in accordance with these Regulations, regularly inspect the implementation of the regulations on biosafety, and regularly inspect, maintain and update the facilities, equipment and materials of the laboratory, in order to ensure its compliance with the State standards.

The establisher of a laboratory and the competent department thereof shall strengthen the supervision of the daily activities of the laboratory.

Article 32 The responsible person of a laboratory shall assume the primary responsibility for its biosafety.

A laboratory shall strictly comply with the standards of the State and the laboratory technical rules and operation practice in its laboratory activities. The responsible person of the laboratory shall assign a full-time person to supervise and inspect its compliance with laboratory technical rules and operation practice.

Article 33 The establisher of a laboratory conducting laboratory activities related to highly pathogenic microorganisms shall establish and improve its security system, adopt security measures, strictly guard against any theft, robbery, loss or leakage of highly pathogenic microorganisms, so as to ensure the security of the laboratory and pathogenic microorganisms in its possession. In case of any theft, robbery, loss or leakage of highly pathogenic microorganisms in the laboratory, the establisher of the laboratory shall make a report thereon in accordance with Article 17 of these Regulations.

A laboratory conducting laboratory activities related to highly pathogenic microorganisms shall report to the local public security organ for the record and shall accept the supervision and guidance therefrom for the security of the laboratory.

Article 34 A laboratory or its establisher shall regularly train staff members every year, so as to ensure their mastery of laboratory technical rules, operation practice, biosafety knowledge and operation skills; and the organize the assessment therefor. Staff members may take their positions only after having passed the assessment.

A laboratory conducting laboratory activities related to highly pathogenic microorganisms shall report every six month to the competent health department or the competent veterinary department of people's government of the province, autonomous region, or municipality directly under the Central Government on the training and assessment of its staff members and the operation of the laboratory.

Article 35 Laboratory activities related to highly pathogenic microorganisms

shall be conducted by two or more staff members.

Staff members or other persons concerned shall obtain the approval of the responsible person of the laboratory before they enter a laboratory for laboratory activities related to highly pathogenic microorganisms. The laboratory shall provide them with protection equipment that meets the requirements for protection and adopt other professional protection measures. The laboratory for conducting laboratory activities related to highly pathogenic microorganisms shall keep the health of its staff members under surveillance, organize annual physical examination and set up health files for them. When necessary, preventive vaccination shall be conducted for the staff members.

Article 36 Within a given time period, laboratory activities related to one type of highly pathogenic microorganisms shall be only conducted in one and the same independent safe area of a given laboratory.

Article 37 A laboratory shall set up files to record the use and safety supervision of the laboratory. The files of laboratory activities related to highly pathogenic microorganisms shall be kept for not less than 20 years.

Article 38 A laboratory shall, in accordance with laws, administrative regulations, and provisions of the relevant departments of the State Council on environmental protection, dispose waste water, waste gas and other waste, and develop appropriate environmental protection measures to prevent environmental pollution.

Article 39 A laboratory of Biosafety Level 3 or Biosafety Level 4 shall display the biohazard signs and the signs indicating its Biosafety Level at a conspicuous place, as required by the competent health department or the competent veterinary department of the State Council.

Article 40 A laboratory conducting laboratory activities related to highly pathogenic microorganisms shall work out a preparedness plan against laboratory infection emergencies, and report the plan for the record to the competent health department or the competent veterinary department of the people's government of the province, autonomous region, or municipality directly under the Central Government

where the laboratory is located.

Article 41 The competent health department and the competent veterinary department of the State Council shall, jointly with the relevant departments of the State Council, establish the State Experts' Committee on Biosafety of Pathogenic Microorganism Laboratories, which shall be composed of experts of etiology, immunology, inspection medicine, epidemiology, preventive veterinary medicine, environmental protection, laboratory management, etc. The Committee shall conduct biosafety assessment, technical consultation and deliberation on the establishment and operation of laboratories conducting laboratory activities related to highly pathogenic microorganisms.

The competent health department and the competent veterinary department of the people's government of the province, autonomous region or municipality directly under the Central Government shall, jointly with the relevant departments of the people's government at the same level, establish the Experts' Committee on Biosafety Pathogenic Microorganism Laboratories in its own locality, which shall be composed of experts of etiology, immunology, inspection medicine, epidemiology, preventive veterinary medicine, environment protection, laboratory management, etc. The Committee shall conduct technical consultation on the establishment and operation of local laboratories.

Chapter IV Control of Laboratory Infection

Article 42 The establisher of a laboratory shall designate a specialized institution or individual to control laboratory infection, conduct regular inspections on the laboratory in terms of its implementation of the bylaws on laboratory biosafety protection, on storage and use of bacteria (virus) strains and samples of pathogenic microorganisms, on safe operation, and on disposal of waste water, waste gas and other waste.

Any institution or individual responsible for control of laboratory infection shall possess adequate knowledge on the control of infectious diseases related to the

pathogenic microorganisms in the laboratory, and make regular inquiries as to health status of the laboratory staff.

Article 43 Where any staff member of a laboratory exhibits the clinical symptom or physical sign of infection attributable to the laboratory activities related to highly pathogenic microorganisms in the laboratory, the responsible person of the laboratory shall report the matter to the institution or individual responsible for laboratory infection control and promptly assign a specific person to escort the staff member in question for diagnosis and treatment. The staff member in question shall give a truthful account of the specific type of pathogenic microorganisms that he has recently contacted and its risk level to the medical institution for diagnosis and treatment. The medical institution that admits the infected staff member as a patient shall administer prompt medical treatment. If the conditions of the medical institution do not permit appropriate treatment, the medical institution shall, as required, transfer the patient to another medical institution qualified for the treatment of infectious diseases, and the qualified medical institution shall admit the patient and shall not refuse.

Article 44 In case of any leakage of highly pathogenic microorganisms in a laboratory, the staff members thereof shall take prompt control measures to prevent the spread of highly pathogenic microorganisms, and, at the same time, report the matter to the institution or individual responsible for laboratory infection control.

Article 45 The institution or individual responsible for laboratory infection control shall, upon receipt of a report referred to in Articles 43 and 44 of these Regulations, immediately activate the preparedness plan against laboratory infection emergencies and initiate an investigation on the biosafety status of the laboratory concerned. Where laboratory infection or leakage of highly pathogenic microorganisms is ascertained, a report thereon shall be submitted as required in Article 17 of these Regulations, control measures shall be adopted, medical observation or quarantined treatment shall be applied to staff members involved, and the laboratory shall be sealed up to prevent the spread.

Article 46 Upon receipt of a report on infection of staff members of a laboratory

or on leakage of pathogenic microorganisms, or, upon finding that an infection accident occurs in a laboratory conducting laboratory activities related to pathogenic microorganisms, the competent health department or the competent veterinary department shall promptly organize the efforts of the disease prevention and control institution, the animal epidemic control and supervision institution, medical institution and all other institutions concerned to adopt the following prevention and control measures according to law:

- (1) to seal up the laboratory contaminated by pathogenic microorganisms or the place that is likely to cause spread of pathogenic microorganisms;
- (2) to conduct epidemiological investigation;
- (3) to quarantine the patients for treatment and conduct medical examination for other persons concerned;
- (4) to place close contacts under medical observation;
- (5) to conduct field disinfection;
- (6) to quarantine or stamp out the infected animals or animals suspected of being infected; and
- (7) to take other necessary prevention and control measures.

Article 47 Where an medical or veterinary institution, or any of its medical or veterinary personnel on duty finds a case or suspected case of a human or animal infectious disease attributable to laboratory infection of highly pathogenic microorganisms, the medical or veterinary institution in question shall, within two hours, report the matter to the competent health department or the competent veterinary department of the local people's government at the county level. Upon receipt of the report, the competent health department or the competent veterinary department shall, within two hours, notify the matter to the competent health department or the competent veterinary department of the people's government at the county level of the place where the laboratory concerned is located. Upon receipt of the notification, the competent health department or the competent veterinary department shall take prevention and control measures as required in Article 46 of these Regulations.

Article 48 Where the spread of pathogenic microorganisms is likely to cause the outbreak of an infections disease, the competent health department or the competent veterinary department of the people’s government at or above the county level shall handle the situation in accordance with the relevant laws and administrative regulations, and the preparedness plan against laboratory infection.

Chapter V Supervision and Administration

Article 49 The competent health department and the competent veterinary department of the local people’s government at or above the county level shall, in accordance with division of their functions, perform the following functions and duties:

(1)supervising and inspecting the collection, transportation and storage of bacteria (virus) strains or samples of pathogenic microorganisms;

(2)supervising and inspecting laboratories conducting laboratory activities related to highly pathogenic microorganisms in terms of their compliance with the conditions set forth by these Regulations;

(3)supervising and inspecting laboratories and establishers thereof in terms of the training and assessment of their staff members and those having taken their posts; and

(4)supervising and inspecting laboratories in terms of their compliance with the standards of the State, technical rules and operation practice in the laboratory activities related to pathogenic microorganisms.

The competent health department and the competent veterinary department of the local people’s government at or above the county level shall perform their functions and duties of supervision and administration mainly through the examination of records, files and reports that indicate the compliance with the relevant laws, administrative regulations, and standards of the State and requirements.

Article 50 When performing its functions and duties of supervision and inspection, the competent health department or the competent veterinary department

of the local people's government at or above the county level shall have the power to enter the units under inspection and the scenes of leakage or spread of pathogenic microorganisms, to collect evidence or samples, and to consult and copy relevant materials. Where there is a need to enter a laboratory conducting laboratory activities related to highly pathogenic microorganisms for collection of evidence or samples, a specialized institution shall be designated or commissioned to do the job. The units under inspection shall be cooperative and shall not refuse or obstruct it.

Article 51 The certification and accreditation regulatory department of the State Council shall supervise and inspect the accreditation of laboratories in accordance with the Regulations of the People's Republic of China on Certification and Accreditation.

Article 52 The competent health department, the competent veterinary department and the competent environmental protection department shall perform their respective functions and duties in accordance with the statutory competence and procedures, and maintain justice, impartiality, openness, good manner and efficiency.

Article 53 In the law-enforcement by the competent health department, the competent veterinary department or the competent environmental protection department, two or more law-enforcement officials shall be assigned therefor and they shall show their law-enforcement credentials, and make the relevant law-enforcement documents as required.

The documents such as the record of field inspection or sample collection shall, after verification, be signed by the law-enforcement officials and the person inspected or the person from whom samples are collected. Where the person inspected or the person from whom samples are collected refuses to sign his name on the relevant documents, the law-enforcement officials shall sign their name thereon and have an explanatory note attached.

Article 54 The competent health department, the competent veterinary department and the competent environmental protection department, as well as their law-enforcement officials shall, on their own initiative, accept supervision from society and all citizens when performing their functions and duties. Any citizen, legal

person or other organization shall have the right to report to the people's government at a higher level and its competent health department, competent veterinary department and competent environmental protection department, on any violation of relevant provisions by the local people's government or its relevant competent departments in the performance of functions and duties. Upon receipt of the report, the people's government or department concerned shall initiate an investigation and make a disposition thereon in a timely manner.

Article 55 Upon finding a need to handle a matter that falls under the functions and duties of the competent health department, the competent veterinary department or the environmental protection department of the people's government at a lower level, the competent health department, the competent veterinary department or the competent environmental protection department of the people's government at a higher level shall notify the department concerned to handle such matter in a timely manner. If the competent health department, the competent veterinary department or the environmental protection department of the people's government at a lower level fails to handle the matter in a timely manner or fails to perform its functions and duties in an active manner, the competent health department, the veterinary department or the environmental protection department of the people's government at a higher level shall order it to make corrections in a specified time limit; if no corrections are made in the specified time limit, the competent health department, the veterinary department or the environmental protection department of the people's government at a higher level shall have the power to handle the matter directly.

Chapter VI Legal Liability

Article 56 Where a laboratory of Biosafety Level 3 or Biosafety Level 4 that has not obtained the qualification certificate for conducting laboratory activities related to highly pathogenic microorganisms conducts laboratory activities related to certain highly pathogenic microorganisms or suspected highly pathogenic microorganisms, or, a laboratory of Biosafety Level 3 or Biosafety Level 4 with such qualification

certificate conducts laboratory activities related to certain highly pathogenic microorganisms or suspected highly pathogenic microorganisms without approval, the competent health department or the competent veterinary department of the local people's government at or above the county level shall, in accordance with the functions and duties thereof, order the laboratory in question to stop the relevant activities, supervise it destroying the pathogenic microorganisms used in laboratory activities or transferring them to a resource institution, and give it a warning. If the spread of infectious diseases or any other serious result is thus caused, the principal responsible person of the laboratory, the persons in charge bearing direct responsibility and other persons directly responsible therefor shall, in accordance with law, be dismissed from office or discharged from public employment by the establisher of the laboratory. If the laboratory in question has the qualification certificate, such qualification certificate shall be revoked. If a crime is thus constituted, criminal liability shall be investigated according to law.

Article 57 Where, in violation of these Regulations, the competent health department or the competent veterinary department approves a laboratory that does not meet the conditions set forth in these Regulations to conduct laboratory activities related to highly pathogenic microorganisms, the department that grants the approval shall revoke such approval, order the laboratory in question to immediately stop the relevant activities, supervise it destroying the pathogenic microorganisms used in laboratory activities or transferring them to a resource institution, and give an administrative sanction to the persons in charge bearing direct responsibility and other persons directly responsible therefor. If a crime is thus constituted, criminal liability shall be investigated according to law.

Where the lawful rights and interests of a party concerned are violated due to the illegal grant of approval, the competent health department or the competent veterinary department that grants the approval shall bear the liability of compensation according to law.

Article 58 Where the competent health department or the competent veterinary department fails to issue the qualification certificate for conducting laboratory

activities related to highly pathogenic microorganisms to a laboratory that meets the conditions set forth in these Regulations, or fails to, within the statutory time limit, make a decision whether or not to approve the application of an entry-exit inspection and quarantine institution for conducting further testing activities on highly pathogenic microorganisms or suspected highly pathogenic microorganisms in a laboratory, which is urgently needed, the administrative organ at a higher level or the supervisory organ shall order the department in question to make corrections and give it a warning. If the spread of infectious diseases or any other serious result is thus caused, the persons in charge bearing direct responsibility and other persons directly responsible therefor shall, in accordance with law, be given an administrative sanction of dismissal from office or discharge from public employment. If a crime is thus constituted, criminal liability shall be investigated according to law.

Article 59 Where, in violation of these Regulations, a laboratory that does not meet the requirements for biosafety conducts laboratory activities related to pathogenic microorganisms, the competent health department or the competent veterinary department of the local people's government at or above the county level shall, in accordance with the functions and duties thereof, order the laboratory in question to stop the relevant activities, supervise it destroying the pathogenic microorganisms used in the laboratory activities or transferring them to a resource institution, and give it a warning. If the spread of infectious diseases or any other serious result is thus caused, the principal responsible person of the laboratory in question, the persons in charge bearing direct responsibility and other persons directly responsible therefor shall, in accordance with law, be dismissed from office or discharged from public employment by the establisher of the laboratory. If a crime is thus constituted, criminal liability shall be investigated according to law.

Article 60 Where a laboratory commits any of the following acts, the competent health department or the competent veterinary department of the local people's government at or above the county level shall, in accordance with the functions and duties thereof, order the laboratory in question to make corrections in a specified time limit and give it a warning. If no corrections are made in the specified time limit, the

principal responsible person of the laboratory in question, the persons in charge bearing direct responsibility and other persons directly responsible therefor shall, in accordance with law, be dismissed from office or discharged from public employment by the establisher of the laboratory. If the laboratory in question has a license document, such document shall be revoked by the original licensing department:

(1) failing to display the biohazard signs or the signs indicating its Biosafety Level at a conspicuous place as required by the competent health department or the competent veterinary department of the State Council;

(2) failing to report the results and other information on the laboratory activities to the original approving department;

(3) failing to collect samples of pathogenic microorganisms as required, or failing to keep a detailed record of the source of the collected samples, the process of the collection, methodology applied, or other information concerned;

(4) failing to report the construction, alteration or extension of a laboratory of Biosafety Level 1 or Biosafety Level 2 to the competent health department or the competent veterinary department of the people's government of at the level of a city divided into districts for the record;

(5) failing to regularly train its staff members as required, allowing staff members who have not passed the assessment to take their posts, or allowing persons to enter the laboratory without taking any protection measures;

(6) its staff members fail to comply with the technical rules or operation practice on laboratory biosafety;

(7) failing to set up or keep files of its laboratory activities as required; or

(8) failing to work out the preparedness plan against laboratory infection emergencies and submit such plan for the record as required.

Article 61 Where the establisher of a laboratory that is approved according to law to conduct laboratory activities related to highly pathogenic microorganisms fails to establish and improve the security system or fails to adopt security measures, the competent health department or the competent veterinary department of the local people's government at or above the county level shall, in accordance with the

functions and duties thereof, order it to make corrections in a specified time limit and give it a warning. If no corrections are made and thus the bacteria (virus) strains or samples of highly pathogenic microorganisms are stolen or robbed or other serious results are caused, the laboratory's qualification certificate for conducting laboratory activities related to highly pathogenic microorganisms shall be revoked by the original issuing department. In addition, if the spread of infectious diseases is thus caused, the persons in charge bearing direct responsibility and other persons directly responsible therefor of the establisher of the laboratory shall be demoted, dismissed from office or discharged from public employment by the competent department of the establisher of the laboratory. If a crime is thus constituted, criminal liability shall be investigated according to law.

Article 62 Where anyone transports bacteria (virus) strains or samples of highly pathogenic microorganisms without approval, or, the carrier that is approved to transport bacteria (virus) strains or samples of highly pathogenic microorganisms fails to perform the duties of protection, thus causing the theft, robbery, loss or leakage of bacteria (virus) strains or samples of highly pathogenic microorganisms, the competent health department or the competent veterinary department of the local people's government at or above the county level shall, in accordance with the functions and duties thereof, order it to adopt necessary measures, eradicate the hidden dangers, and give it a warning. If the spread of infectious diseases or any other serious result is thus caused, the principal responsible person, the persons in charge bearing direct responsibility and other persons directly responsible therefor shall, in accordance with law, be dismissed from office or discharged from public employment by the competent department of the consignor or the carrier. If a crime is thus constituted, criminal liability shall be investigated according to law.

Article 63 Under any of the following circumstances, the competent health department or the competent veterinary department of the local people's government at or above the level of a city divided into districts of the place where the laboratory in question is located shall, in accordance with the functions and duties thereof, order the unit in question to immediately stop the illegal acts, supervise it destroying the

pathogenic microorganisms or transferring them to a resource institution. If the spread of infectious diseases or any other serious result is thus caused, the principal responsible person of the unit, the persons in charge bearing direct responsibility and other persons directly responsible therefor shall, in accordance with law, be dismissed from office or discharged from public employment by the unit that they belong to or the competent department thereof. If the unit in question has a license document, such documents shall be revoked by the original licensing department. If a crime is thus constituted, criminal liability shall be investigated according to law:

(1) upon the conclusion of relevant laboratory activities, a laboratory fails to promptly destroy bacteria (virus) strains or samples of pathogenic microorganisms on the spot or transfer them to a resource institution;

(2) a laboratory conducts laboratory activities related to highly pathogenic microorganisms with new technology and methodology without prior deliberation by the State Experts' Committee on Biosafety of Pathogenic Microorganism Laboratories;

(3) anyone, without approval, conducts laboratory activities related to pathogenic microorganisms that have not been detected in the country or the pathogenic microorganisms that has been announced eradicated in the country;

(4) anyone, in a specialized laboratory that is not designated, conducts laboratory activities related to pathogenic microorganisms that have not been detected in the country or the pathogenic microorganisms that has been announced eradicated in the country; or

(5) within a given time period, laboratory activities related to two or more types of highly pathogenic microorganisms are conducted in on and the same independent safe area of a given laboratory.

Article 64 Where the accreditation body accredits a laboratory that does not comply with the State standards for laboratory biosafety and the conditions set forth in these Regulations, or refuses to accredit a laboratory that complies with the State standards for laboratory biosafety and the conditions set forth in these Regulations, the certification and accreditation regulatory department of the State Council shall

order the body in question to make corrections within a specified time limit and give it a warning. If the spread of infectious diseases or any other serious result is thus caused, the certification and accreditation regulatory department of the State Council shall disqualify the body from conducting accreditation, and the principal responsible person of the body, the persons in charge bearing direct responsibility and other persons directly responsible therefor shall, in accordance with law, be dismissed from office or discharged from public employment by the competent department thereof, if any. If a crime is thus constituted, criminal liability shall be investigated according to law.

Article 65 Where any staff member of a laboratory exhibits the clinical symptom or physical sign of infection attributable to the laboratory activities of the laboratory related to highly pathogenic microorganisms or any leakage of highly pathogenic microorganisms occurs in the laboratory, but the responsible person or staff members of the laboratory, or the institution or individual responsible for laboratory infection control fails to make reports as required or fails to adopt control measures as required, the competent health department or the competent veterinary department of the local people's government at or above the county level shall, in accordance with the functions and duties thereof, order him to make corrections within a specified time limit and give him a warning. If the spread of infectious diseases or any other serious result is thus caused, the principal responsible person of the laboratory, the persons in charge bearing direct responsibility and other persons directly responsible therefor shall, in accordance with law, be dismissed from office or discharged from public employment by the establisher of the laboratory. If the laboratory in question has a license document, such document shall be revoked by the original licensing department. If a crime is thus constituted, criminal liability shall be investigated according to law.

Article 66 Where anyone refuses the investigation or sampling that is related to the spread of highly pathogenic microorganisms or refuses the prevention or control measures adopted in accordance with these Regulations by the competent health department or the competent veterinary department, the competent health department

or the competent veterinary department of the local people's government at or above the county level shall, in accordance with the functions and duties thereof, order it to make corrections within a specified time limit and give it a warning. If the spread of infectious diseases or any other serious result is thus caused, the principal responsible person of the laboratory, the persons in charge bearing direct responsibility and other persons directly responsible therefor shall, in accordance with law, be demoted, dismissed from office or discharged from public employment by the establisher of the laboratory. If the laboratory in question has a license document, such document shall be revoked by the original licensing department. If a crime is thus constituted, criminal liability shall be investigated according to law.

Article 67 Where any carrier, escort, resource institution, or establisher of a laboratory fails to report, as required by these Regulations, any theft, robbery, loss or leakage of pathogenic microorganisms, the competent health department or the competent veterinary department of the local people's government at the county level shall give it a warning. If the spread of infectious diseases or any other serious result is thus caused, the principal responsible person thereof, the persons in charge bearing direct responsibility and other persons directly responsible therefor shall, in accordance with law, be dismissed from office or discharged from public employment by the establisher of the laboratory or the competent department of the carrier or resource institution. If a crime is thus constituted, criminal liability shall be investigated according to law.

Article 68 Where a resource institution fails to store bacteria (virus) strains or samples transferred from a laboratory in accordance with relevant provisions, or, fails to provide bacteria (virus) strains or samples in accordance with relevant provisions, its designating department shall order it to make corrections and recall the bacteria (virus) strains or samples that are illegally provided. If the spread of infectious diseases or any other serious result is thus caused, the principal responsible person of the institution, the persons in charge bearing direct responsibility and other persons directly responsible therefor shall, in accordance with law, be dismissed from office or discharged from public employment by the unit that they belong to or the

competent department thereof. If a crime is thus constituted, criminal liability shall be investigated according to law.

Article 69 Where the relevant competent department of the people's government at or above the county level fails to perform, as required by these Regulations, the duty of supervising and inspecting laboratories and laboratory activities that they conduct, the relevant people's government shall, within the functions and duties thereof, order the department in question to make corrections, and circulate a notice of critics. If the spread of infectious diseases or any other serious result is thus caused, the persons in charge bearing direct responsibility shall, in accordance with law, be given an administrative sanction. If a crime is thus constituted, criminal liability shall be investigated according to law.

Chapter VII Supplementary Provisions

Article 70 Laboratories of the armed forces shall be subject to the supervision and administration by the competent health department of the Chinese People's Liberation Army with reference to these Regulations.

Article 71 Laboratories established prior to the effective date of these Regulations shall, within six months from the effective date of these Regulations, complete the relevant formalities in accordance with these Regulations.

Article 72 These Regulations shall be effective as of the date of promulgation.