

## Measures for the Bio-safety Environmental Management of Pathogenic Microbe Laboratories

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Order of the State Environmental Protection Administration  
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The “Measures for the Bio-safety Environmental Management of Pathogenic Microbe Laboratories”, which were adopted at the second working meeting of the State Environmental Protection Administration on March 2, 2006, are hereby promulgated, and shall come into force on May 1, 2006.

State Environmental Protection Administration Director General Zhou Shengxian  
March 8, 2006

### Measures for the Bio-safety Environmental Management of Pathogenic Microbe Laboratories

Article 1 The present measures are formulated in accordance with the “Regulation on the Bio-safety Management of Pathogenic Microbe Laboratories” and other relevant laws and administrative regulations on environmental protection for the purpose of regulating the bio-safety environmental management of pathogenic microbe laboratories (hereinafter referred to as “laboratories”).

Article 2 The present measures shall apply to the bio-safety environmental management of the laboratories within the territory of the People’s Republic of China and their experimental activities.

The term “pathogenic microbe” as mentioned in the present measures refers to any microorganism capable of causing human or animal diseases.

The term “experimental activities” as mentioned in the present measures refers to the activities which are conducted in the laboratories, such as research, teaching, testing and diagnosis relating to the strains or samples of pathogenic bacterium (viruses).

Article 3 The state classifies the laboratories into Level 1, Level 2, Level 3 and Level 4 in light of their pathogenic microbe bio-safety protection levels as well as the national standards for the bio-safety of laboratories:

No Level 1 or Level 2 laboratory may conduct experimental activities relating to highly pathogenic microbes.

Article 4 The State Environmental Protection Administration shall formulate and promulgate the laboratory pollution control standards, the environmental management technical norms, and the environmental supervision and inspection system.

Article 5 The State Environmental Protection Administration establishes an experts committee for

bio-safety environmental management of pathogenic microbe laboratories. The experts committee shall be mainly composed of experts in the areas of environmental protection, pathogenic microbes, and laboratory management.

The main duties of the experts committee for bio-safety environmental management of pathogenic microbe laboratories include: deliberating the relevant laboratory pollution control standards, environmental management technical norms, and proposing the deliberation suggestions; examining the relevant laboratory environmental impact assessment documents, and proposing the examination suggestions.

Article 6 Whoever intends to newly build, rebuild or expand a laboratory shall, in accordance with the provisions of the state on environmental protection, implement the environmental impact assessment system.

A laboratory's environmental impact assessment documents shall analyze and forecast the impacts which might be caused from pathogenic microbe experimental activities to the environment, and shall propose the preventive and control measures.

Article 7 Whoever intends to newly build, rebuild or expand a Level 3 or Level 4 laboratory or to produce or import a movable Level 3 or Level 4 laboratory shall work out an environmental impact report, and submit it pursuant to the prescribed procedures to the State Environmental Protection Administration for examination and approval.

An environmental impact assessment institution undertaking environmental impact assessment of Level 3 or Level 4 laboratories shall have the Grade A assessment eligibility and corresponding assessment scope.

Article 8 A laboratory shall, in accordance with the environmental protection provisions of the state, and in light of the requirements of the approved environmental impact assessment documents and reply documents of the environmental protection administrative department, install or fit out the facilities and equipment for prevention and control of pollution.

The facilities and equipment for prevention and control of pollution must be found qualified from inspection of the environmental protection administrative department before the laboratory puts them into operation or use.

Article 9 A Level 3 or Level 4 laboratory which has been built and is accredited by the state shall, within 15 days after obtaining the bio-safety laboratory certificate, fill out the Form of Archival Filing of Level 3 and Level 4 Pathogenic Microbe Laboratories (see the attached form), and submit it to the environmental protection administrative department of the local people's government at the county level.

Article 10 The environmental protection administrative department of a people's government at the county level shall, within 10 days as of receipt of the Form of Archival Filing of Level 3 and Level 4 Pathogenic Microbe Laboratories, report it to the environmental protection administrative department of the people's government at the districted city level; the environmental protection administrative department of the people's government at the districted city level shall, within 10 days as of receipt of the Form of Archival Filing of Level 3 and Level 4 Pathogenic Microbe Laboratories, report it to the environmental protection administrative department of the people's government at the provincial level; and the environmental protection administrative department of the people's government at the provincial level shall, within 10 days as of receipt of the Form of Archival Filing of Level 3 and Level 4 Pathogenic Microbe Laboratories, report to the State Environmental Protection Administration.

Article 11 A laboratory's establisher shall assume the responsibilities of preventing and controlling the pollution caused from the waste water, waste gas and hazardous wastes due to experimental activities.

A laboratory shall, in accordance with the environmental protection provisions of the state, as well as the laboratory pollution control standards, and the requirements of environmental management technical norms, establish and improve the rules on prevention and control of pollution from its waste water, waste gas and hazardous wastes, and shall be staffed with full-time (part-time) employees to inspect, supervise and effect the conformity of the disposal of its waste water, waste gas and hazardous wastes to the laws, administrative regulations of the state and the present Measures.

Article 12 Where a laboratory intends to discharge waste water or waste gas, it shall comply with the relevant provisions of the State Environmental Protection Administration, and implement the system for report and registration of discharged pollutants.

Where a laboratory causes hazardous wastes, it must, in accordance with the relevant provisions on prevention and control of pollution from hazardous wastes to the environment, report the relevant information on the category, quantity, destination, storage and disposal, etc. of the hazardous wastes to the environmental protection administrative department of the local people's government at the county level or above.

Article 13 A laboratory must make innocuous treatment of its waste water in accordance with the relevant provisions of the state; and shall not discharge waste water until it meets the relevant standards of the state for discharge.

Article 14 A laboratory must, when conducting experimental activities, ensure the normal operation of the facilities for prevention and control of air pollution in accordance with the relevant provisions of the state; and the discharged waste gas shall not violate the relevant standards or provisions of the state.

Article 15 A laboratory must, in accordance with the following provisions, appropriately collect, store and dispose of the hazardous wastes caused from its experimental activities so as to prevent environmental pollution:

(1) It shall establish a hazardous waste registration system, and register the hazardous wastes it has caused. The registered contents shall include the sources, categories, weight or quantity of the hazardous wastes, the disposal ways, the final whereabouts, and the signature of the handler, etc. The registered information shall be preserved for at least 3 years.

(2) It shall timely collect the hazardous wastes caused from its experimental activities, and put them by categories into special packages and containers which meet the relevant environmental protection requirements of the state and can prevent leakage and resist penetration by sharp instruments, and shall set obvious warning marks and statements on hazardous wastes in light of the requirements of the state.

(3) It shall fit out tanks (boxes) or other facilities or equipment meeting the requirements of the laws and administrative regulations of the state and relevant technical norms for temporary storage of hazardous wastes.

(4) It shall, in accordance with the relevant provisions of the state, make innocuous treatment of the hazardous wastes on the spot, and shall, in compliance with the principle of nearby centralized disposal, timely deliver the innocuously treated hazardous wastes to the entity with the lawful permit for business operation of hazardous wastes for centralized disposal.

(5) If it intends to transfer hazardous wastes, it shall, in accordance with the "Law of on the Prevention and Control of Environmental Pollution by Solid Wastes" and the relevant provisions of the State Environmental Protection Administration, implement the multi-form system for transferring hazardous wastes.

(6) It shall not discard, dump or pile up hazardous wastes at will, or mix the hazardous wastes into other wastes or domestic refuse. And

(7) It shall meet other requirements in the environmental protection laws, administrative regulations and rules of the state on the management of hazardous wastes.

Article 16 The experiment archives established and preserved by a laboratory shall truthfully record the experimental activities relevant to bio-safety and the information on the working state of the facilities and equipment, as well as the information on the innocuous treatment, centralized disposal and inspection of the waste water, waste gas and hazardous wastes caused from experimental activities.

Article 17 A laboratory shall make an environmental pollution emergency plan, and submit it to the environmental protection administrative department of the local people's government at the county level for archival filing, and make regular drills.

Where a laboratory causes hazardous wastes, it shall, in accordance with the provisions of the state on prevention and control of pollution caused from hazardous wastes to the environment, make the measures for prevention of unexpected accidents and the emergency plan, and shall submit them to the environmental protection administrative department of the local people's government at the county level or above for archival filing.

The Level 3 laboratories which have been put into use before the "Regulation on the Bio-safety Management of Pathogenic Microbe Laboratories" came into force shall, in light of the requirements of the environmental protection administrative department of the local people's government at the county level, make the environmental pollution emergency plan and the monitoring plan within a time limit, and submit them to the environmental protection administrative department for archival filing.

Article 18 Where a laboratory meets with leakage or diffusion, and has caused or might cause serious environmental pollution or ecological destruction, it shall immediately take emergency responding measures, circularize the matter to the entities and residents who might be harmed, and report to the environmental protection administrative department of the local people's government and other relevant departments and accept investigation and punishment.

The environmental protection administrative department of a local people's government shall, pursuant to the procedures prescribed by the State Environmental Protection Administration for reporting pollution accidents, report to the environmental protection administrative department of the people's government at the higher level.

Article 19 The environmental protection administrative department of each people's government at the county level or above shall, at regular intervals, supervise and inspect the prevention and control of pollution caused from waste water, waste gas and hazardous wastes of laboratories within its own jurisdictional scope. If it finds any illegal act, it shall order the laboratory concerned to make a rectification within a time limit. The inspection information and the settlement results shall be recorded, and shall, after signed by the inspectors, be put into archives and fed back to the inspected entity.

Article 20 The environmental protection administrative department of a people's government at the county level or above shall, when performing the supervision and inspection duties, have the right to enter the inspected entity or the pathogenic microbe leakage or diffusion spot to make investigations, collect evidence, draw samples, and consult or copy relevant documents, while the inspected entity shall cooperate with, instead of refusing or obstructing the said administrative department.

Where the environmental protection administrative department of a people's government at the

county level or above needs to enter a Level 3 or Level 4 laboratory to make investigations, collect evidence, or draw samples, it shall designate or entrust a professional institution to do so.

The environmental protection administrative department shall maintain the technical secrets and business secrets for laboratories.

Article 21 Where any laboratory violates the relevant provisions of the present Measures and is under any of the following circumstances, it shall be ordered by the environmental protection administrative department of the people's government at the county level or above to make a correction within a time limit, and be admonished; if it fails to make a correction within the time limit, it shall be fined 1,000 Yuan or less:

- (1) It fails to establish the rules for the management of prevention and control of pollution, or fails to be staffed with full-time (part-time) employees;
- (2) It fails to have its hazardous wastes registered, or fails to preserve the registration documents; or
- (3) It fails to make an environmental pollution emergency plan.

If, for other violations prescribed in the present Measures, there are already penalty provisions in any environmental protection law or administrative regulation, such provisions shall apply.

Article 22 The environmental protection administrative department shall timely announce to the public the name list of the laboratories penalized under the present Measures, and circularize the said name list to China National Accreditation Board for Laboratories.

Article 23 The present Measures shall come into force on May 1, 2006.

Appendix: Form of Archival Filing of Level 3 and Level 4 Pathogenic Microbe Laboratories  
(Omitted)