Regulations on the Administration of Laboratory Animals

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Chapter I — General Provisions

Article 1 — These Regulations are formulated for the purpose of strengthening the administration of laboratory animals, ensuring the quality of laboratory animals, and meeting the needs of scientific research, economic development and social progress.

Article 2 — For the purposes of these Regulations, “laboratory animals” means animals that are artificially bred, whose carried microorganisms are controlled, and whose genetic background is definite or whose source is clear, and that are used for scientific research, teaching, production, testing and other scientific experiments.

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Article 3 — These Regulations apply to entities and individuals engaged in the research, breed preservation, rearing, supply, use, administration and supervision of laboratory animals.

Article 4 — The administration of laboratory animals shall follow the principle of unified planning and rational division of labor, and be conducive to promoting the scientific research and use of laboratory animals.

Article 5 — The State Science and Technology Commission shall be in charge of laboratory animal work nationwide.

The science and technology commissions of provinces, autonomous regions and municipalities directly under the Central Government shall be in charge of laboratory animal work within their respective regions.

The relevant departments of the State Council shall be responsible for the administration of laboratory animal work within their respective departments.

Article 6 — The state shall implement a system of quality supervision and quality conformity certification for laboratory animals. The specific measures shall be formulated separately by the State Science and Technology Commission.

Article 7 — The national standards for laboratory animals in genetics, microbiology, nutrition and rearing environment shall be formulated by the State Bureau of Technical Supervision.

Chapter II — Rearing Administration of Laboratory Animals

Article 8 — Entities engaged in the rearing of laboratory animals shall, in accordance with the standards for genetics, microbiology, nutrition and rearing environment, periodically conduct quality monitoring of laboratory animals. There shall be complete and accurate records of all operational processes and monitoring data, and a statistical reporting system shall be established.

Article 9 — The rearing rooms and laboratories of laboratory animals shall be located in separate areas and strictly isolated.

The rearing rooms and laboratories of laboratory animals shall have scientific management systems and operating procedures.

Article 10 — The breed preservation and rearing of laboratory animals shall use varieties and strains recognized domestically or abroad, and hold valid conformity certificates.

Article 11 — Laboratory animals shall be reared separately according to different sources, different varieties and strains, and different experimental purposes.

Article 12 — Laboratory animals are divided into four grades: grade one, ordinary animals; grade two, clean animals; grade three, specific-pathogen-free animals; and grade four, germ-free animals.

Laboratory animals of different grades shall be administered in accordance with the corresponding microbial control standards.

Article 13 — Laboratory animals shall be fed with complete-formula feed of qualified quality. Rotten, spoiled, insect-infested or contaminated feed shall not be used to feed laboratory animals. Vegetables, fruits and the like used directly as feed shall be washed, disinfected and kept fresh.

Article 14 — The drinking water of grade-one laboratory animals shall conform to the sanitary standards for urban domestic drinking water. The drinking water of grade-two, grade-three and grade-four laboratory animals shall conform to the sanitary standards for urban domestic drinking water and be sterilized.

Article 15 — The bedding of laboratory animals shall be treated in accordance with the needs of laboratory animals of different grades so as to be clean, dry, absorbent, non-toxic, pest-free, infection-free and contamination-free.

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Chapter III — Quarantine of Laboratory Animals and Control of Infectious Diseases

Article 16 — Laboratory animals introduced shall be subject to isolation quarantine.

Wild animals captured for the purpose of supplementing breed sources or developing new varieties shall be subject to isolation quarantine at the place of capture and obtain a certificate issued by the animal quarantine department. Wild animals may only enter the laboratory animal rearing rooms after being re-quarantined upon arrival at the laboratory animal premises.

Article 17 — Laboratory animals for which preventive vaccination is necessary shall be vaccinated in accordance with the experimental requirements or the relevant provisions of the Animal Epidemic Prevention Law of the People's Republic of China, except for laboratory animals used as raw materials for biological products.

Article 18 — Where laboratory animals fall ill and die, the cause shall be promptly ascertained, properly handled and recorded.

Where laboratory animals contract an infectious disease, they shall be immediately destroyed or isolated and treated according to the circumstances. For laboratory animals that may be infected, emergency preventive vaccination shall be carried out; the areas inside and outside the rearing rooms that may be contaminated shall be subject to strict disinfection measures; and the matter shall be reported to the higher-level laboratory animal administration department and the local animal quarantine and health and epidemic prevention entities, which shall take emergency preventive measures to prevent the spread of the epidemic.

Chapter IV — Use of Laboratory Animals

Article 19 — In using laboratory animals, the corresponding qualified laboratory animals shall be selected according to different experimental purposes. When applying for scientific research projects and appraising scientific research achievements, the use of qualified laboratory animals shall be treated as a basic condition. The testing or safety evaluation results obtained using unqualified laboratory animals shall be invalid, and the products produced shall not be used.

Article 20 — Laboratory animals provided for use shall have the following complete materials:

(1) the exact names of the variety, strain and substrain;

(2) the genetic background or its source;

(3) the microbial testing status;

(4) the conformity certificate; and

(5) the signature of the person in charge of the rearing entity.

Laboratory animals without the aforesaid materials shall not be used.

Article 21 — The transport of laboratory animals shall be attended by special personnel. The loading and transport tools for laboratory animals shall be safe and reliable. Laboratory animals of different varieties, strains or grades shall not be transported in mixed loads.

Chapter V — Administration of the Import and Export of Laboratory Animals

Article 22 — Laboratory animals imported from abroad as original breeds shall be accompanied by materials such as the names of the strains and substrains, and the genetic and microbial status, issued and signed by the person in charge of the rearing entity.

Laboratory animals without the aforesaid materials shall not be imported or used.

Article 23 — For the export of laboratory animals developed using wildlife species under key state protection, the export procedures may only be handled after obtaining an export license in accordance with the relevant provisions of the state.

Article 24 — The quarantine of imported and exported laboratory animals shall be handled in accordance with the Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine.

Chapter VI — Personnel Engaged in Laboratory Animal Work

Article 25 — Laboratory animal work entities shall, according to needs, be staffed with scientific and technical personnel and professionally trained rearing personnel. All categories of personnel shall comply with the various systems for the rearing and administration of laboratory animals and be familiar with and master the operating procedures.

Article 26 — Laboratory animal work entities shall periodically organize physical examinations for staff who come into direct contact with laboratory animals. Personnel who contract an infectious disease and are unfit for the work they undertake shall be promptly reassigned.

Article 27 — Personnel engaged in laboratory animal work shall take good care of laboratory animals and shall not tease or mistreat them.

Chapter VII — Rewards and Penalties

Article 28 — Entities or individuals that have been engaged in the rearing and administration of laboratory animals for a long time and have achieved outstanding results shall be commended or rewarded by the departments in charge of laboratory animal work.

Article 29 — Entities violating these Regulations shall be given, by the departments in charge of laboratory animal work, administrative penalties of a warning, ordered improvement within a time limit, or ordered closure, depending on the seriousness of the circumstances.

Article 30 — The relevant staff violating these Regulations shall be given administrative sanctions by their employing entities, depending on the seriousness of the circumstances and in accordance with the relevant provisions of the state.

Chapter VIII — Supplementary Provisions

Article 31 — The people's governments of provinces, autonomous regions and municipalities directly under the Central Government and the relevant departments of the State Council may, in accordance with these Regulations and in light of the specific circumstances, formulate implementation measures.

The administration of laboratory animals in the military system shall be implemented by reference to these Regulations.

Article 32 — These Regulations shall be interpreted by the State Science and Technology Commission.

Article 33 — These Regulations shall take effect on the date of promulgation.

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