

Measures for the Examination and Approval of the Bio-Safety Administration of Highly Pathogenic Animal Pathogenic Microbe Labs

Promulgation date: 05-20-2005
Effective date: 05-20-2005
Department: MINISTRY OF AGRICULTURE
Subject: OTHER PROVISIONS

Order of the Ministry of Agriculture
(No. 52)

The Measures for the Examination and Approval of the Bio-safety Administration of Highly Pathogenic Animal Pathogenic Microbe Labs, which were adopted at the 10th executive meeting of the Ministry of Agriculture upon deliberation, are hereby promulgated and shall come into force as of the date of Promulgation.

Minister Du Qinglin
May 20, 2005

Measures for the Examination and Approval of the Bio-Safety Administration of Highly Pathogenic Animal Pathogenic Microbe Labs

Chapter I General Provisions

Article 1 The present Measures are formulated according to the Regulation on the Bio-safety Management of Pathogenic Microbe Labs in order to regulate the examination and approval for the bio-safety administration of highly pathogenic animal pathogenic microbe labs.

Article 2 The examination and approval of qualification and experimental activities of highly pathogenic animal pathogenic microbe labs and transportation of highly pathogenic animal pathogenic microbe shall be governed by the present Measures.

Article 3 The term “highly pathogenic animal pathogenic microbes” as mentioned in the present Measures refers to the microbes in categories I and II as prescribed in the Classified Catalog of Animal Pathogenic Microbes that root in animals.
The Classified Catalog of Animal Pathogenic Microbes shall be formulated, amended and promulgated by the Ministry of Agriculture in collaboration with the relevant departments of the State Council.

Article 4 The Ministry of Agriculture shall take charge of the bio-safety administration of highly pathogenic animal pathogenic microbe labs in the whole country.
The administrative departments of veterinary of the people’s government at or above the county level shall take charge of the bio-safety administration of highly pathogenic animal pathogenic microbe labs within the administrative divisions thereof.

Chapter II Examination and Approval of Lab Qualification

Article 5 Where a lab engages in any experimental activity concerning highly pathogenic animal pathogenic microbes, it shall obtain the Qualification Certificate of Highly Pathogenic Animal Pathogenic Microbe Labs as issued by the Ministry of Agriculture.

Article 6 Where a lab applies for the Qualification Certificate of Highly Pathogenic Animal Pathogenic Microbe Labs, it shall meet the following requirements:
(1) It engages in such activities as researches, testing, diagnosis, and storage of bacterium (virus) strains concerning any animal epidemic disease according to law;
(2) It meets the requirements of the Regulation on the Safety Administration of Veterinary Labs as

promulgated by the Ministry of Agriculture;

- (3) It has obtained the national accreditation certificates of safe bio-labs of Grade III or IV;
- (4) The personnel thereof that engage in experimental activities shall have academic background at or above junior college or professional titles above mid-grade in relevant majors related to veterinary and have received bio-safety trainings; and
- (5) The engineering quality of the lab has passed inspection and acceptance according to law.

Article 7 An applicant that meets the requirements as prescribed in the preceding Article may file an application to the local administrative department of veterinary of the people's government of the province, autonomous region or municipality directly under the Central Government and submit the following materials:

- (1) The Qualification Application Form for Highly Pathogenic Animal Pathogenic Microbe Labs in duplicate;
- (2) Management brochure of the lab;
- (3) A photocopy of the accreditation certificate of a national lab;
- (4) A photocopy of the legal-person qualification certificate of the entity that establishes the lab;
- (5) Photocopies of the certificates of educational background and professional title of the personnel thereof;
- (6) Certification materials regarding bio-safety trainings for the personnel thereof; and
- (7) A photocopy of the inspection and acceptance report on the engineering quality of the lab.

The administrative department of veterinary of the people's government of the province, autonomous region or municipality directly under the Central Government shall report the opinion of its preliminary examination and the relevant materials to the Ministry of Agriculture within 10 days as of acceptance of the said application.

Where the Ministry of Agriculture has received the preliminary examination opinion and the relevant materials, it shall organize an expert appraisal. Where necessary, the Ministry of Agriculture may go to the spot for verification and evaluation. The Ministry of Agriculture shall, within 10 days as of acceptance of the experts' appraisal opinion, decide whether to issue the Qualification Certificate of Highly Pathogenic Animal Pathogenic Microbe Labs. Where it refuses to grant an approval, it shall inform the applicant of the result and give explanations.

Article 8 The valid term of the Qualification Certificate of Highly Pathogenic Animal Pathogenic Microbe Labs is 5 years. Upon the expiration of the valid term, where a lab needs to continue its experimental activities regarding highly pathogenic animal pathogenic microbes, it shall, 6 months before the expiration, file a new application for the Qualification Certificate of Highly Pathogenic Animal Pathogenic Microbe Labs according to the provisions of the present Measures.

Chapter III Examination and Approval of Lab Activities

Article 9 The labs of Grade I or II shall not engage in any experimental activity regarding highly pathogenic animal pathogenic microbes. Where any lab of Grade III or IV needs to engage in a certain experimental activity regarding highly pathogenic animal pathogenic microbes or any suspected one, it shall be subject to the approval of the Ministry of Agriculture or the administrative department of veterinary of the people's government of the province, autonomous region or municipality directly under the Central Government.

Article 10 Where a lab of Grade III or IV engages in a certain experimental activity regarding highly pathogenic animal pathogenic microbes or any suspected one, it shall meet the following requirements:

- (1) It has obtained the Qualification Certificate of Highly Pathogenic Animal Pathogenic Microbe Labs, which is within its valid term; and
- (2) Its experimental activities shall be restricted to relevant researches, testing, diagnosis, and storage of bacterium (virus) strains and samples.

Where there is any clear provision on the special experimental entity that engages in highly

pathogenic animal pathogenic microbes or any suspected one by the Ministry of Agriculture, the said activity shall be carried out only in the prescribed labs.

Article 11 An applicant that meets the requirements as prescribed in the preceding Article may file an application to the local administrative department of veterinary of the people's government of the province, autonomous region or municipality directly under the Central Government and submit the following materials:

- (1) The Application Form for Experimental Activities of Highly Pathogenic Animal Pathogenic Microbe Labs in duplicate;
- (2) A photocopy of the Qualification Certificate of Highly Pathogenic Animal Pathogenic Microbe Labs; and
- (3) For any scientific project concerning highly pathogenic animal pathogenic microbes, the certification materials of the initiative document thereof shall also be provided.

For any experimental activity involving any animal pathogenic microbe that hasn't appeared in China so far or that has been announced to be eliminated, or involving any separation and appraisal of special highly pathogenic animal pathogenic microbes, cultivation of live virus, the pick-up of nucleic acid from infectious materials and animal inoculation, the administrative department of veterinary of the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 7 days as of acceptance of the relevant application, report the preliminary examination opinion and the relevant materials to the Ministry of Agriculture. The Ministry of Agriculture shall, within 8 days as of acceptance of the preliminary examination opinion and the relevant materials, decide whether or not to approve it. In the case of disapproval, it shall inform the relevant applicant of the result and give explanations.

For any experimental activity involving any other highly pathogenic animal pathogenic microbe or any suspected one other than those as prescribed in the preceding paragraph, the administrative department of veterinary of the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 15 days as of acceptance of the relevant application, decide whether or not to grant an approval and report it to the Ministry of Agriculture for archival filing within 10 days as of approval; in the case of disapproval, it shall inform the relevant applicant of the result and give explanations.

Article 12 Before a lab applies for or accepts any scientific project concerning highly pathogenic animal pathogenic microbes, it shall apply to the Ministry of Agriculture for examination and submit the following materials:

- (1) The Examination Form for Bio-safety of Scientific Projects concerning Highly Pathogenic Animal Pathogenic Microbes in duplicate;
- (2) Suggestion of Scientific Projects; and
- (3) Measures for bio-safety in researches of scientific projects.

The Ministry of Agriculture shall decide whether to grant an approval within 20 days as of acceptance of the said application.

Where a scientific project is initiated and requires the relevant experimental activities concerning highly pathogenic animal pathogenic microbes, it shall be subject to the approval of the Ministry of Agriculture or the administrative department of veterinary of the people's government of the province, autonomous region or municipality directly under the Central Government according to the provisions of Articles 10 and 11 of the present Measures.

Article 13 Where an entry-exit inspection and quarantine institution or animal epidemic prevention institution carries out inspection and diagnosis and if any highly pathogenic animal pathogenic microbe or any suspected one is found and thus, it needs to further undertake such relevant experiments as separation and appraisal of special highly pathogenic animal pathogenic microbes, cultivation of live virus, pick-up of nucleic acid from infectious materials and animal inoculation, it shall be subject to the approval of the Ministry of Agriculture or the administrative department of veterinary of the people's government of the province, autonomous region or municipality directly under the Central Government for approval according to the provisions of Articles 10 and 11 of the

present Measures.

Article 14 Where an entry-exit inspection and quarantine institution, for the purpose of satisfying the requirement of any emergency in the work of inspection and quarantine, applies for undertaking such further experiments as separation and appraisal of special highly pathogenic animal pathogenic microbes, cultivation of live virus, pick-up of nucleic acid from infectious materials and animal inoculation in the lab, it shall meet the following requirements and file an application according to Article 11 of the present Measures:

- (1) The purpose of the experiment shall be limited to quarantine;
- (2) The experimental activities shall comply with the statutory procedures for quarantine; and
- (3) It has obtained the Qualification Certificate of Highly Pathogenic Animal Pathogenic Microbe Labs, which is within its valid term.

The Ministry of Agriculture or the administrative department of veterinary of the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 2 hours as of acceptance of the said application, decide whether or not to approve it; in the case of disapproval, it shall inform the applicant of the result and give explanations. Where it fails to make a decision within 2 hours, the lab of entry-exit inspection and quarantine institution may undertake the relevant experimental activities.

Article 15 The lab shall, in the process of experimental activities, abide by the Regulation on the Bio-safety Management of Pathogenic Microbe Labs and do a good job in the control of lab infection, bio-safety protection and the storage and use of microbe (virus) strains, safe operation, disposal of wasted water, gas or any other wastes as let out from the lab.

Article 16 After an experiment is concluded, the lab shall destroy the microbe (virus) strains or samples on the spot or transfer them to the preservation institution as designated by the Ministry of Agriculture for storage, and report the experimental results and the relevant work to the original department that has granted the approval.

Chapter IV Examination and Approval of Transportation

Article 17 Any transportation of highly pathogenic animal pathogenic microbe (virus) strains or samples shall be subject to the approval of the Ministry of Agriculture or the administrative department of veterinary of the people's government of the province, autonomous region or municipality directly under the Central Government.

Article 18 For any transportation of highly pathogenic animal pathogenic microbe (virus) strains or samples, the following conditions shall be satisfied:

- (1) The use of highly pathogenic animal pathogenic microbe (virus) strains or samples to be transported shall be restricted to such activities as researches, testing, diagnosis, and storage of bacterium (virus) strains and production of biological products for animal uses;
- (2) Where the receiving institution is an institution of researches, testing or diagnosis, it shall obtain the Qualification Certificate of Highly Pathogenic Animal Pathogenic Microbe Labs as issued by the Ministry of Agriculture and obtain the approval document to engage in experimental activities of highly pathogenic animal pathogenic microbes or the suspected ones as issued by the administrative department of veterinary of the people's government of the province, autonomous region or municipality directly under the Central Government; where the receiving entity is a development and production entity of biological products for animal uses, it shall obtain the approval document of biological products as issued by the Ministry of Agriculture; where the receiving entity is a preservation institution of bacterium (virus) strains, it shall obtain the designation document for preservation of bacterium (virus) strains as issued by the Ministry of Agriculture.
- (3) The containers containing highly pathogenic animal pathogenic microbe (virus) strains or samples or the packing materials thereof shall comply with the Rules of Packing Materials of Highly Pathogenic Animal Pathogenic Microbe (Virus) Strains or Samples as prescribed by the Ministry of

Agriculture.

Article 19 An applicant that meets the requirements of the preceding Article may file an application to the administrative department of veterinary of the people's government of the province, autonomous region or municipality directly under the Central Government at the departure place and submit the following materials:

- (1) The Application Form for the Transportation of Highly Pathogenic Animal Pathogenic Microbe (Virus) Strains (Samples) in duplicate;
- (2) The photocopies of the relevant approval documents as prescribed in item (2) of the preceding Article; and
- (3) The certification materials that the receiving entity has agreed to receive them, with the exception of any delivery of bacterium (virus) strains for preservation.

For any transportation within the administrative division of the people's government of the province, autonomous region or municipality directly under the Central Government, the administrative department of veterinary of the people's government of the province, autonomous region or municipality directly under the Central Government shall carry out an examination on the application materials as submitted by the applicant. For anyone that meets the requirements, the approval shall be granted instantly and the Approval Certificate of Transportation of Highly Pathogenic Animal Pathogenic Microbe (Virus) Strains (Samples) shall be issued; in the case of disapproval, the relevant applicant shall be informed instantly.

For any transportation goes beyond a province, autonomous region or municipality directly under the Central Government or beyond the border, the administrative department of veterinary of the people's government of the province, autonomous region or municipality directly under the Central Government at the departure place shall carry out a preliminary examination and shall report the opinion of preliminary examination and the relevant materials to the Ministry of Agriculture. The Ministry of Agriculture shall carry out an examination on the preliminary opinion and the relevant materials. For those that meet the requirements, the approval shall be granted instantly and the Approval Certificate of Transportation of Highly Pathogenic Animal Pathogenic Microbe (Virus) Strains (Samples) shall be issued; in the case of disapproval, the relevant applicant shall be informed instantly.

Article 20 An applicant may carry out the transportation of highly pathogenic animal pathogenic microbe (virus) strains or samples on the strength of the Approval Certificate of Transportation of Highly Pathogenic Animal Pathogenic Microbe (Virus) Strains (Samples); where the transportation requires such public transportation tools as railway, road and civil aviation, he shall go through the formalities for undertaking transportation on the strength of the Approval Certificate of Transportation of Highly Pathogenic Animal Pathogenic Microbe (Virus) Strains (Samples); where the transportation is carried out by civil aviation, it shall be subject to the approval of the administrative department of civil aviation of the State Council.

Article 21 Any transportation of samples of animal pathogenic microbes in the course of quarantine by an entry-exit inspection and quarantine institution shall be subject to the approval of the entry-exit inspection and quarantine institution of the State Council and shall be reported to the Ministry of Agriculture.

Chapter V Supplementary Provisions

Article 22 For any violation of the present Measures, punishments shall be given according to the provisions of Articles 56, 57, 58, 59, 60, 62, and 63 of the Regulation on the Bio-safety Management of Pathogenic Microbe Labs.

Article 23 The Qualification Certificate of Highly Pathogenic Animal Pathogenic Microbe Labs, the Approval for Experimental Activities of Highly Pathogenic Animal Pathogenic Microbe Labs and the Approval Certificate of Transportation of Highly Pathogenic Animal Pathogenic Microbe (Virus)

Strains (Samples) shall be uniformly printed by the Ministry of Agriculture.
The Application Form for the Qualification of Highly Pathogenic Animal Pathogenic Microbe Labs, the Application Form for Experimental Activities of Highly Pathogenic Animal Pathogenic Microbe Labs, the Application Form for the Transportation of Highly Pathogenic Animal Pathogenic Microbe (Virus) Strains (Samples) and the Bio-safety Examination Form of Scientific Projects concerning Highly Pathogenic Animal Pathogenic Microbes may be downloaded from China Agricultural Information Net (<http://www.agri.gov.cn>).

Article 24 The present Measures shall come into force as of the day of promulgation.