

Unclassified

[Show Full Version](#) 

PRC S&T: MOH Rules on Transport of Pathogenic Bacteria, Viruses, Specimens

CPP20060320300006 Beijing Jiankang Bao in Chinese 06 Feb 06 pp 1, 7

[Report by Wang Lei-Fei: "Special Requirements for Transporting Pathogenic Micro-organisms"; and Order No. 45 of Department of Health, People's Republic of China: "Regulations for Transporting Infectious and Highly Pathogenic Human Microorganisms, Bacteria, Viruses, or Specimens"]



Special Requirements for Transporting Pathogenic Microorganisms

Regulations for Transport Management and Registry of Highly Pathogenic Microorganisms Issued

Recently, based on the order titled *Regulations for Transport Management of Infectious and Highly Pathogenic Human Microorganisms, Bacteria, Viruses, or Specimens* issued by the 45th Director of the Department of Health, and the publication of a *Registry of Infectious and Pathogenic Human Microorganisms*, the State Council is implementing the *Regulations for Pathogenic Microorganisms and Laboratory Organisms Safety Control* to reinforce the safe management of laboratory organisms.

According to the recommendations, the first part of our country's *Registry of Infectious and Pathogenic Human Microorganisms* was drafted and revised for release by the Department of Health after consulting with various departments in the State Council. This registry has collected a total of 380 strains of infectious and pathogenic human microorganisms, including 160 stains of viruses, 155 strains of bacteria, 59 strains of fungus, and six strains of special pathogens like mad cow disease. Pathogenic microorganisms in this registry are classified mainly based on taxonomy, degree of harmfulness, laboratory safety level required for laboratory activities with these organisms, and transport packaging requirements. This registry has a significant and important meaning in directing virus cultivation, animal infection experiments, and the safe handling of other laboratory organisms.

It is also reported that *Regulations for Transport Management of Infectious and Highly Pathogenic Human Microorganisms, Bacteria, Viruses, or Specimens* will go into effect on 1 February 2006. The infectious and highly pathogenic human microorganisms, bacteria, viruses, and specimens indicated in the Regulations are those with Type One harmfulness, like the Yellow Fever virus, and Type Two pathogenic microorganisms, bacteria, viruses, or specimens, like the highly pathogenic bird flu virus and **Anthrax** spout bacillus, included in the Registry of Infectious and Pathogenic Human Microorganisms. Microorganisms, bacteria, viruses, and specimens with Type Three harmfulness are in the Registry of Infectious and Pathogenic Human Microorganisms, but have a Class A transport packaging requirement, like Hepatitis B virus, and those ambiguous highly pathogenic microorganisms, bacteria, viruses, or specimens should also be managed according to the transport regulations. These regulations indicate that when transporting highly pathogenic microorganisms, bacteria, viruses, or specimens, permission should be obtained from the Administrative Office in the Department of Health above the provincial level; without such permission, no transport should take place. Offenders will be punished according to the applicable *Articles of Regulations for Pathogenic Microorganism and Laboratory Organism Safety Management* by the State Council.

(For the complete *Regulations for Transport Management of Infectious and Highly Pathogenic Human Microorganisms, Bacteria, Viruses, or Specimens*, see Seventh Edition.)

Regulations for Transport Management of Infectious and Highly Pathogenic Human Microorganisms, Bacteria, Viruses, or Specimens

Order Number 45 From the Department of Health of the People's Republic of China.

"Regulations for Transport Management of Infectious and Highly Pathogenic Human Microorganisms, Bacteria, Viruses, or Specimens" was passed at the meeting of the Department of Health on 24 November 2005. It is now ready for release and implementation starting on 1 February 2006.

Director, Gao Qiang. December 28, 2005

Regulation 1: These regulations are formulated based on the infectious disease prevention and treatment methods of the People's Republic of China, the *Regulations for Transport Management of Pathogenic Microorganisms and Safety Management of Laboratory Organisms*, and regulations of other laws and administrative statutes in order to reinforce the transport management of infectious and highly pathogenic human microorganisms, bacteria, viruses, or specimens and ensure public health and hygiene.

Regulation 2: The so-called infectious and highly pathogenic human microorganisms, bacteria, viruses, or specimens in these regulations are the Type One and Type Two pathogenic microorganisms, bacteria, viruses, or specimens in the *Registry of Infectious and Pathogenic Human Microorganisms, Bacteria, Viruses, or Specimens*.

Regulation 3: These regulations apply to work involving transport management of contagious and highly pathogenic microorganisms, bacteria, viruses, or specimens.

The transport of Type Three pathogenic microorganisms, bacteria, viruses, or specimens, as listed in the *Registry of Infectious and Pathogenic Human Microorganisms* with a Class A packaging requirement, and the ambiguous highly pathogenic microorganisms, bacteria, viruses, or specimens should be transported and managed according to this regulation.

Regulation 4: When transporting bacteria, viruses, or specimens (which will have a general designation of highly pathogenic microorganisms, bacteria, viruses, or specimens from here on) as listed in Regulation Three, permission should be obtained from the Administrative Office in the Department of Health at the provincial level or higher. Without such permission, transportation should not take place.

Regulation 5: When an organization is conducting disease control and prevention, medical treatment, teaching, scientific research, bacteria or virus preservation, and biological product production due to the work requirement, a permit can be applied for to transport highly pathogenic microorganisms, bacteria, viruses, or specimens.

Regulation 6: The organization applying for a permit to transport the highly pathogenic microorganisms, bacteria, viruses, or specimens (referred to as the applicant hereafter) should submit the application to the Administrative Office in the provincial Department of Health before transporting these materials. The following materials (one original and three reproduced copies) should also be included in the application:

- 1) Application form for transporting infectious and highly pathogenic human microorganisms, bacteria, viruses, or specimens.
- 2) Proof of personnel qualification (one reproduced copy).
- 3) Proof of an agreement from the receiving organization (referred to as the recipient hereafter) to accept the highly pathogenic microorganisms, bacteria, viruses, or specimens.
- 4) Reproduced copies of the proof documents as required in Items Two and Three in Regulation Seven.
- 5) The permit serial number of the container or packaging material, a reproduced copy of the certificate of inspection or the certificate of promise to undertake the transporting container or packaging material carrying the highly pathogenic microorganisms, bacteria, viruses, or specimens.
- 6) All other applicable materials as required.

Regulation 7: The recipient should meet the following requirements:

- 1) There should be qualified personnel in the recipient's organization.
- 2) The laboratory should be equipped and qualified to conduct experiments with the highly pathogenic microorganisms.

3) A permit should be obtained from the government office in charge of licensing experiments on highly pathogenic microorganisms, preservation of bacteria, viruses, and specimens, and biological products.

Regulation 8: A permit for multiple transports of the same strain of highly pathogenic microorganism, bacteria, virus, or specimen between the same applicant and recipient can be requested. This multiple transport permit is good for six months and can be renewed if necessary.

Regulation 9: Applications for transporting highly pathogenic microorganisms, bacteria, viruses, or specimens within a province or autonomous region or an administrative area of a municipality directly under the Central Government will have to be approved directly by the Administrative Office in the Department of Health of that province, autonomous region, or municipality directly under the Central Government.

The Administrative Office in the Department of Health at the provincial level should promptly examine the application materials submitted by the applicants and immediately notify the applicants about supplementing materials in the case of incomplete applications or correcting documentation that does not conform to legal formalities. Applications that are complete and conform to legal formalities should be accepted promptly, and decisions should be made within five business days as to whether approval will be granted. For those that conform to the legal requirements, Certificates of Approval for transporting infectious and highly pathogenic human microorganisms, bacteria, viruses, or specimens should be issued. And for applications which do not meet the legal requirements, explanations should be given as to why an approval was denied.

Regulation 10: For transport of highly pathogenic human microorganisms, bacteria, viruses, or specimens extending beyond a province, autonomous region, or administrative area of a municipality directly under the Central Government, the application materials should be submitted to the Administration Office in the Department of Health of the transport originating province for initial examination. For those that meet the requirements, the Administrative Office in the Department of Health at the provincial level should notify the applicants of the initial examination opinions within three business days and forward the initial examination opinions and application materials to the Ministry of Health for approval.

The Department of Health should make a decision on whether an approval will be granted within three business days after the application materials are received. For those that meet the legal requirements, a Certificate of Approval should be issued for transporting infectious and highly pathogenic human microorganisms, bacteria, viruses, or specimens. For applications which do not meet the legal requirements, explanations of the decision of disapproval should be given.

Regulation 11: For applications to transport highly pathogenic microorganisms, bacteria, viruses, or specimens in order to control outbreaks of infectious diseases, flu, or the sudden occurrence of a public health incident which requires emergency management, the Administrative Office in the provincial Department of Health can forward the report, examination, and approval to the Ministry of Health *viac facsimile*. The required original copies of the applicable materials should be submitted and completed as soon as possible after the event took place.

Based on the requirements of the disease control projects, the highly pathogenic microorganisms, bacteria, viruses, or specimens should be sent to the Chinese Centers for Disease Control and Prevention, and the applications should be submitted directly to the Chinese Centers for Disease Control and Prevention for approval. For those that meet the legal criteria, a Certificate of Approval will be issued for transporting infectious and highly pathogenic human microorganisms, bacteria, viruses, or specimens. And for those that do not meet the legal requirements, a notice with an explanation of the disapproval decision should be given. The Chinese Centers for Disease Control and Prevention should provide the status of the examination and approval to the Department of Health for the record within three days.

Regulation 12: The containers or packaging materials used for transporting highly pathogenic microorganisms, bacteria, viruses, or specimens should meet the regulations for Class A packaging standards as detailed in the International Civil Aviation Organization's Document 9284 Packaging Instructions PI602, "Detailed Techniques for Safely Transporting Dangerous Goods by Air"; meet the requirements of being waterproof, damage-resistant, leakage-proof, high temperature-resistant, and high pressure-resistant, and be stamped with the Department of Health-approved Biological Danger label, mark, transport registry, warning wording, and prompt phrases.

Regulation 13: Someone must be put in charge of escorting the transport of the highly pathogenic microorganisms, bacteria, viruses, or specimens, and the number of escort personnel should not be less than two. The applicant should provide training to the escort personnel on the applicable knowledge of biological safety and take the corresponding preventive measures during the escort process.

Regulation 14: The applicant should use the Certificate of Approval for transporting infectious and highly pathogenic

human microorganisms, bacteria, viruses, or specimens issued by the Administrative Office in the Department of Health above the provincial level or the Chinese Centers for Disease Control and Prevention as proof in handling the procedures with the Civil Aviation and other offices for transport of the dangerous goods.

To transport dangerous goods through Civil Aviation, the consigner should follow the rules of Dangerous Goods Transport by Air in the Chinese Civil Aviation Regulations (CCAR276) and meet the requirements detailed in *Document of Aviation Safety and Techniques for Dangerous Goods Transport* (Doc 9824) by the International Civil Aviation Organization, properly categorize, pack, mark, label, submit the properly filled out the Dangerous Goods Transport by Air Document, and hand it over to a Department of Civil Aviation -approved air carrier and airport for transport. If the transport has to be done by an air carrier through an airport that have not yet been approved by the Department of Civil Aviation, then permission has to be obtained from the Department of Civil Aviation first.

Regulation 15: Packing of the highly pathogenic microorganisms, bacteria, viruses, or specimens before shipment and unpacking of the package after it is received have to be done in a location that meets biological safety regulations.

The applicant should thoroughly check the container and package to see if it meets the safety requirements before transport, if all the container and packaging labels and specimen registry are complete and without errors, and if the orientation of the container is set properly.

Regulation 16: After the transport, the applicant should submit a written report of the transport situation to the original approving office.

Regulation 17: For behaviors violating these regulations, punishment will be given according to Regulations 62 and 67 and the applicable *Regulations of Pathogenic Microorganisms and Safety Management of Laboratory Organisms*.

Regulation 18: Import and export of highly pathogenic microorganisms, bacteria, viruses, or specimens should be managed according to the "Notice on Reinforcing the Management and Health Quarantine of Import and Export of Special Medical Products" by the Department of Health and the National Quality Testing Institute.

Regulation 19: These regulations will go into effect on 1 February 2006.

[Description of Source: Beijing Jiankang Bao in Chinese -- daily newspaper of the Ministry of Public Health, covering medical research, epidemiology, and public health problems]

Attachments:
[w100317e.pdf](#)

THIS REPORT MAY CONTAIN COPYRIGHTED MATERIAL. COPYING AND DISSEMINATION IS PROHIBITED WITHOUT PERMISSION OF THE COPYRIGHT OWNERS.

Unclassified