# Regulations of the People's Republic of China on Export Control of Dual-Use Biological Agents and Related Equipment and Technologies

(Promulgated by Decree No. 365 of the State Council of the People's Republic of China on October 14, 2002, and effective as of December 1, 2002)

Article 1These Regulations are formulated for the purposes of strengthening export control of dual-use biological agents and related equipment and technologies, and safeguarding the State security and social and public interests.

Article 2The export of dual-use biological agents and related equipment and technologies referred to in these Regulations means the export for trade of dual-use biological agents and related equipment and technologies listed in the "Dual-Use Biological Agents and Related Equipment and Technologies Export Control List" (hereinafter referred to as the Control List) attached to these Regulations, and the exchange with, interchange with, gift to, exhibition in, assistance to, provision of service for as such and other forms of technological transfer thereof to foreign countries and regions.

Article 3The export of dual-use biological agents and related equipment and technologies shall be in accordance with relevant laws, administrative regulations of the State and these Regulations, and shall not imperil the State security and social and public interests.

Article 4The State shall exercise strict control on the export of dual-use biological agents and related equipment and technologies so as to prevent dual-use biological agents and related equipment and technologies from being used for the purpose of biological weapons.

Article 5The State shall practice a licensing system for the export of dual-use biological agents and related equipment and technologies in the Control List. Without being licensed, no unit or individual shall export such dual-use biological agents and related equipment and technologies.

Article 6Exporters of dual-use biological agents and related equipment and technologies shall register themselves with the competent department in charge of foreign economic relations and trade of the State Council (hereinafter referred to as the competent foreign economic and trade department of the State Council). Without such registration, no unit or individual shall export dual-use biological agents and related equipment and technologies. The specific measures for such registration shall be formulated by the competent foreign economic and trade department of the State Council.

Article 7The receiving party of dual-use biological agents and related equipment and technologies shall guarantee:

(1) not to use the imported dual-use biological agents and related equipment and technologies for the purpose of biological weapons;

(2) not to use dual-use biological agents and related equipment and technologies supplied by China for the purposes other than the declared end-use without the consent of the Chinese Government; and

(3) not to transfer dual-use biological agents and related equipment and technologies to any third party other than the declared end-user without the consent of the Chinese Government.

Article 8Anyone who intends to export dual-use biological agents and related equipment and technologies listed in the Control List shall apply to the competent foreign economic and trade department of the State Council, fill in the export application form for dual-use biological agents and related equipment and technologies (hereinafter referred to as the export application form), and submit the following documents:

(1) identifications of the applicant's legal representative, chief manager(s) and the person(s) handling the deal;

(2) duplicates of the contract or agreement, or other certification documents;

(3) technical specifications of the dual-use biological agents and related equipment and technologies;

(4) certificates of end-user and end-use;

(5) documents of guarantee as defined in Article 7 of these Regulations; and

(6) other documents as may be required by the competent foreign economic and trade department of the State Council.

Article 9An applicant shall truthfully fill in the export application form.

Export application forms shall be uniformly produced by the competent foreign economic and trade department of the State Council.

Article 10The competent foreign economic and trade department of the State Council shall, from the date of receiving the export application form and the documents set forth in Article 8 of these Regulations, examine the application, or examine the application jointly with other relevant departments.

The competent foreign economic and trade department of the State Council shall, within 15 working days, make a decision of approval or denial of the application for the export of dual-use biological agents and related equipment and technologies listed in Part I of the Control List; the competent foreign economic and trade department of the State Council shall, within 45 working days, make a decision of approval or denial of the application for the export of dual-use biological agents and related equipment and technologies listed in Part II of the Control List.

Article 11Where the export of dual-use biological agents and related equipment and technologies entails significant impact on the State security and social and public interests, the competent foreign economic and trade department of the State Council shall, jointly with relevant departments, submit the case to the State Council for approval.

Where the export of dual-use biological agents and related equipment and technologies is submitted to the State Council for approval, the timing restrictions set forth in Article 10 of these Regulations shall not be applied.

Article 12Where an application for the export of dual-use biological agents and related equipment and technologies is examined and approved, the competent foreign economic and trade department of the State Council shall issue a licence for the export of dual-use biological agents and related equipment and technologies (hereinafter referred to as an export licence), and notify the Customs in writing.

Article 13An export licence holder who intends to change the dual-use biological agents and related equipment and technologies originally applied for export shall return the original export licence and file a new application to obtain an export licence according to relevant provisions of these Regulations.

Article 14While exporting dual-use biological agents and related equipment and technologies, the exporter shall present the export licence to the Customs, complete the customs procedures and accept supervision and control of the Customs in accordance with the provisions of the Customs Law.

Article 15Where the receiving party contravenes the guarantees made according to the provisions of Article 7 of these Regulations, or there is a risk of proliferation of dual-use biological agents and related equipment and technologies listed in the Control List that can be used for the purpose of biological weapons, the competent foreign economic and trade department of the State Council shall suspend or revoke the export licence granted and notify the Customs in writing.

Article 16Where any unit or individual knows or should know that the dual-use biological agents and related equipment and technologies to be exported will be used by the receiving party directly for the purpose of biological weapons, it shall not export such dual-use biological agents and related equipment and technologies, whether included in the Control List or not.

Article 17Upon approval by the State Council, the competent foreign economic and trade department of the State Council may, jointly with relevant departments of the State Council, temporarily decide to exercise export control on specific dual-use biological agents and related equipment and technologies other than those listed in the Control List in accordance with the provisions of these Regulations.

Article 18Those who export dual-use biological agents and related equipment and technologies without being licensed or export dual-use biological agents and related equipment and technologies beyond the scope of the

export licence without authorization, shall be investigated for criminal liability in accordance with the provisions of the criminal law on the crime of smuggling, the crime of illegal business operations, the crime of divulging State secrets or other crimes; if such acts are not serious enough for criminal punishment, by distinguishing different circumstances, they shall be punished in accordance with relevant provisions of the Customs Law, or be given a warning, confiscated of their illegal income, and fined not less than 50,000 yuan but not more than 250,000 yuan by the competent foreign economic and trade department of the State Council; the competent foreign economic and trade department of the State Council may concurrently suspend or even revoke the licensing for their foreign trade operations.

Article 19Those who forge, alter, buy or sell the licence for the export of dual-use biological agents and related equipment and technologies shall be investigated for criminal liability in accordance with the provisions of the criminal law on the crime of illegal business operations or the crime of forging, altering, buying or selling official documents, certificates or seals of a State organ; if such acts are not serious enough for criminal punishment, they shall be punished in accordance with relevant provisions of the Customs Law, and the competent foreign economic and trade department of the State Council may concurrently revoke the licensing for their foreign trade operations.

Article 20Where a licence for the export of dual-use biological agents and related equipment and technologies is obtained by fraud or other illegal means, the competent foreign economic and trade department of the State Council shall revoke such an export licence, confiscate the illegal income, impose a fine of not less than 20,000 yuan but not more than 100,000 yuan, and suspend or even revoke the licensing for their foreign trade operations.

Article 21Where, in violation of the provisions of Article 6 of these Regulations, the export of dual-use biological agents and related equipment and technologies is operated without registration, the competent foreign economic and trade department of the State Council shall ban such illegal activities according to law, and relevant competent departments of the State shall impose punishment thereon in accordance with relevant laws and administrative regulations.

Article 22Where the State functionaries in charge of control on the export of dual-use biological agents and related equipment and technologies abuse their powers, neglect their duties or extort or accept money or properties from others by taking advantage of their positions, they shall be investigated for criminal liability in accordance with the provisions of the criminal law on the crime of abuse of power, the crime of neglect of duties, the crime of accepting bribes and other crimes; if such acts are not serious enough for criminal punishment, they shall be given administrative sanctions according to law.

Article 23In light of actual situations, the competent foreign economic and trade department of the State Council may, jointly with relevant departments, amend the Control List and submit it to the State Council for approval before implementation.

Article 24In the case of the re-export of dual-use biological agents and related equipment and technologies after import, these Regulations shall apply.

Article 25These Regulations shall be effective as of December 1, 2002.

Annex

Dual-Use Biological Agents and Related Equipment and Technologies Export Control List

1. Introduction

(1) This List comprises two parts.

(2) Items controlled in the List are included mainly according to their dual-use specialty in biological area, especially their risk grade for non-peaceful purpose. Thus, biological agents, found or never found, or eradiated in China are all listed in the List.

(3) The pathogens controlled in the List include any isolated living creature of a pathogen agent, and any kind of biological materials (e.g. cell, tissue, serum and animal), or non-biological materials contaminated with these pathogens. Whatever these pathogens are, natural or genetically modified, is under export control, except those in the form of a vaccine.

(4) Toxins controlled in the List do not include immunotoxins, and human medical products approved by the competent department of the State.

(5) Genetic elements controlled in the List include chromosomes, genomes, plasmids, transposons, and vectors whether genetically-modified or unmodified.

(6) Related technologies controlled in the List include technical data and technical assistance and so on, except knowledge in the public domain, or basic scientific research whether controlled in the List, or knowledge required for general patent. The forms of technical data include blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals and instructions written or recorded on other media or devices such as disks, tapes, read-only memories. The forms of technical assistance include offering instruction, skills, training, working knowledge, consulting services, as well as transfer of technical data.

(7) Once the dual-use biological equipment controlled in the List is approved to export, the export of basic technologies related to the equipment, such as installation, operation, maintenance, repair or overhaul to the same end-user is also authorized.

2. Definitions

For the purposes of this List, the following definitions apply:

(1) "Biological dual-use specialty" means the character of being used either for peaceful purposes, such as medicine, prevention, protection, or for non-peaceful purposes, such as development and production of biological weapons. The pathogens, toxins and genetic elements with such character are called dual-use biological agents; and the equipment with such character is called dual-use biological equipment.

(2) "Pathogen" means the natural or genetically-modified pathogenic microorganism which can cause death, disease or other harms to human beings, animals or plants.

(3) "Toxin" means the biological active material, originated from any microorganism, animal or plant, whatever their method of production, whether natural or modified, which can cause death, disease or other harms to human beings, animals, and plants.

(4) "Vaccine" means the medicinal product that has entered into clinical trial, production or marketing as approved by the competent department of the State, which is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or which it is administered.

(5) "Technology" means specific information necessary for the development, production or use of a product.

(6) "Biosafety Level 3 (BL3)" means the containment level and biosafety treatment capabilities that can meet the criteria of BL3 containment as specified in the WHO Laboratory Biosafety Manual (2nd edition, Geneva, 1993) with respect to biological medicine and microbiology facilities in the maintenance of negative air pressure to the environment, access control and the rendering safe of exhaust air and of contaminated material and waste, including effluents by HEPA filtration, microorganism operating regulation and personnel precaution.

(7) "Biosafety Level 4 (BL4)" means the containment level and biosafety treatment capabilities that can meet the criteria of BL4 containment as specified in the WHO Laboratory Biosafety Manual(2nd edition, Geneva, 1993) with respect to biological medicine and microbiology facilities in the maintenance of negative air pressure to the environment, access control and the rendering safe of exhaust air and of contaminated material and waste, including effluents by HEPA filtration, microorganism operating regulation, personnel precaution and so on. The feature is that, on the basis of BL3, the airlock or pass-through autoclave system, biosafety cabinet class III or positive-pressure ventilated suits and a special controlled air system are used to reach a higher biosafety containment and capacity than BL3.

(8) "Basic scientific research" means experimental or theoretical work undertaken principally to acquire new knowledge of the fundamental principles of phenomena or observable facts, not primarily directed towards a specific practical aim or objective.

(9) "Knowledge in the public domain" means technology that has been made available without restrictions upon its further dissemination (copyright restrictions do not remove technology from being in the public

domain).

(10) "Development" is related to all stages before production, such as:

(a) design;

(b) design research;

(c) design analysis;

(d) design concepts;

(e) assembly of prototypes;

(f) pilot production schemes;

(g) design data;

(h) process or transforming design data into a product;

(i) configuration design;

(j) integration design and layouts.

(11) "Production" means all production phases, such as:

(a) construction;

(b) production engineering;

(c) manufacture;

(d) integration;

(e) assembly (mounting);

(f) inspection;

(g) testing;

(h) quality assurance.

(12) "Use" means operation, installation (including on-site installation), maintenance (checking), repair, overhaul, etc.

Part I

1. Human or Zoonotic Pathogens

(1)Bacteria

(a) Clostridium perfringens;

(b) Clostridium tetani;

(c) Enterohaemorrhagic Escherichia coli, serotype O157 and other verotoxin producing serotypes;

(d) Legionella pneumophila;

(e) Yersinia pseudotuberculosis.

(2)Viruses

(a) Kyasanur Forest virus;

(b) Louping ill virus;

(c) Murray Valley encephalitis virus;

(d) Omsk haemorrhagic fever virus;

(e) Oropouche virus;

(f) Powassan virus;

(g) Rocio virus;

(h) St Louis encephalitis virus.

2. Plant Pathogens

(1)Bacteria

(a) Xanthomonas campestris pv. oryzae;

(b) Xylella fastidiosa.

(2)Viruses

Banana bunchy top virus

(3)Fungi

(a) Deuterophoma tracheiphila (syn. Phoma tracheiphila);

(b) Monilia rorei (syn. Moniliophthora rorei).

3. Genetic Elements and Genetically-Modified Organisms

(1)Genetic elements that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms in Part I of the List.

(2)Genetically-modified organisms that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms in Part I of the List.

4. Dual-Use Biological Equipment

(1)Equipment for the micro-encapsulation of live microorganisms and toxins in the range of 1-10 micron particle size, specifically:

(a) interfacial polycondensors;

(b) phase separators.

(2)Fermenters of less than 100 litres capacity with special emphasis on aggregate orders or designs for use in combined systems.

(3)Conventional or turbulent air-flow clean-air rooms and self-contained fan-HEPA filter units that may be used for BL3 or BL4 containment facilities.

5. Related Technology

The technology for development or production of biological agents or dual-use biological equipment in Part I of the List.

Part II

1. Human or Zoonotic Pathogens

(1)Bacteria

(a) Bacillus anthracis;

(b) Brucella abortus;

(c) Brucella melitensis;

(d) Brucella suis;

(e) Chlamydia psittaci;

(f) Clostridium botulinum;

(g) Francisella tularensis;

(h) Burkholderia mallei (Pseudomonas mallei);

(i) Burkholderia pseudomallei (Pseudomonas pseudomallei);

(j) Salmonella typhi;

(k) Shigella dysenteriae;

(l) Vibrio cholerae;

(m) Yersinia pestis.

(2)Viruses

(a) Chikungunya virus;

(b) Congo-Crimean haemorrhagic fever virus;

(c) Dengue fever virus;

(d) Eastern equine encephalitis virus;

(e) Ebola virus;

(f) Hantaan virus;

(g) Junin virus;

(h) Lassa fever virus;

(i) Lymphocytic choriomeningitis virus;

(j) Machupo virus;

(k) Marburg virus;

(l) Monkey pox virus;

(m) Rift Valley fever virus;

(n) Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus);

(o) Variola virus;

(p) Venezuelan equine encephalitis virus;

(q) Western equine encephalitis virus;

(r) White pox;

(s) Yellow fever virus;

(t) Japanese encephalitis virus.

(3)Rickettsiae

(a) Coxiella burnetii;

(b) Bartonella quintana (Rochalimea quintana, Rickettsia quintana);

(c) Rickettsia prowazeki;

(d) Rickettsia rickettsii.

2. Toxins as Follows and Subunits

(1)Botulinum toxins

(2)Clostridium perfringens toxins

(3)Conotoxin

(4)Shiga toxin

(5)Staphylococcus aureus toxins

(6)Tetrodotoxin

(7)Verotoxin

(8)Microcystin (syn. Cyanginosin)

(9)Aflatoxins

(10)Abrin

(11)Cholera toxin

(12)Diacetoxyscirpenol toxin

(13)T-2 toxin

(14)HT-2 toxin

(15)Modeccin toxin

(16)Volkensin toxin

(17)Viscum Album Lectin 1 (syn. Viscumin)

3. Animal Pathogens

(1)Bacteria

Mycoplasma mycoides

(2)Viruses

(a) African swine fever virus;

(b) Avian influenza virus ; (This includes only those Avian influenza viruses of high pathogenicity Type A viruses with an IVPI (intravenous pathogenicity index) in 6-week-old chickens of greater than 1.2 or type A viruses H5 or H7 subtype for which nucleotide sequencing has demonstrated multiple basic amino acids at the cleavage site of haemagglutinin.)

(c) Bluetongue virus;

(d) Foot and mouth disease virus;

(e) Goat pox virus;

(f) Herpes virus (Aujeszky's disease);

(g) Hog cholera virus (syn. swine fever virus);

(h) Lyssa virus;

(i) Newcastle disease virus;

(j) Peste des petits ruminants virus;

(k) Porcine enterovirus type 9 (syn. swine vesicular disease virus);

(l) Rinderpest virus;

(m) Sheep pox virus;

(n) Teschen disease virus;

(o) Vesicular stomatitis virus.

4. Plant Pathogens

(1)Bacteria

(a) Xanthomonas albilineans;

(b) Xanthomonas campestris pv.citri.

(2)Fungi

(a) Colletotrichum coffeanum var. Virulans (Colletotrichum kahawae);

(b) Cochliobolus miyabeanus (Helminthosporium oryzae);

(c) Microcyclus ulei (syn. Dothidella ulei);

(d) Puccinia graminis (syn. Puccinia graminis f.sp.tritici);

(e) Puccinia striiformis (syn. Puccinia glumarum);

(f) Pyricularia grisea/Pyricularia oryzae.

5. Genetic Elements and Genetically-modified Organisms

(1)Genetic elements that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms in Part II of the List.

(2)Genetic elements that contain nucleic acid sequences coding for any of the toxins in Part II of the List, or for their sub-units.

(3)Genetically-modified organisms that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms in Part II of the List.

(4)Genetically-modified organisms that contain nucleic acid sequences coding for any of the toxins in the list or for their sub-units.

6. Dual-Use Biological Equipment

(1)Complete containment facilities at BL3 or BL4 containment level

Complete containment facilities that meet the criteria for BL3 or BL4 containment as specified in the WHO Laboratory Biosafety Manual (2nd edition, Geneva, 1993) should be subject to export control.

(2)Fermenters

Fermenters capable of cultivation of pathogenic microorganisms, viruses or for toxin production, without the propagation of aerosols, having a capacity of 20 litres or greater. Fermenters include bioreactors, chemostats and continuous-flow systems.

(3)Centrifugal Separators (including decanters)

Centrifugal separators capable of continuous separation of pathogenic microorganisms, without the propagation of aerosols, and having all the following characteristics:

(a) one or more sealing joints within the steam containment area;

(b) a flow rate greater than 100 litres per hour;

(c) components of polished stainless steel or titanium;

(d) capable of in-situ steam sterilisation in a closed state.

(4)Cross (tangential) Flow Filtration Equipment

Cross (tangential) flow filtration equipment capable of continuous separation of pathogenic microorganisms, viruses, toxins and cell cultures, having all the following characteristics:

(a) equal to or greater than 5 square metres;

(b) capable of in-situ sterilization.

(5)Freeze-drying Equipment

Steam sterilisable freeze-drying equipment with a condenser capacity of 10 kgs of ice or greater in 24 hours less than 1,000 kgs of ice in 24 hours.

(6)Protective and Containment Equipment

(a) Protective full or half suits or hoods dependent upon a tethered external air supply and operating under positive pressure;

Note: This does not control suits designed to be worn with self-contained breathing apparatus.

(b) Class 3 biological safety cabinets or isolators with similar performance standards (e.g. flexible isolators, dry boxes, anaerobic chambers, glove boxes, or laminar flow hoods (closed with vertical flow)).

(7)Aerosol Inhalation Chambers

Chambers designed for aerosol challenge testing with pathogenic microorganisms, viruses or toxins and having a capacity of 1 cubic metre or greater.

7. Related Technology

The technology for development or production of biological agents or dual-use biological equipment in Part II of the List.