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

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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 ;
(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.