

Control List of Dual-use Biological Equipment and Related Technology and Software

I. Equipment

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1. Complete containment facilities at P3 or P4 containment level

Complete containment facilities that meet the criteria for P3 or P4 (BL3, BL4, L3, L4) containment as specified in the WHO Laboratory Biosafety Manual (3rd edition, Geneva, 2004) should be subject to export control.

2. Fermenters

Fermenters capable of cultivation of pathogenic micro-organisms, 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

Centrifugal separators capable of the continuous separation of pathogenic micro-organisms, 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.

Technical note: Centrifugal separators include decanters.

4. Cross (tangential) Flow Filtration Equipment

Cross (tangential) flow filtration equipment capable of separation of pathogenic micro-organisms, viruses, toxins or cell cultures having all the following characteristics:

- a. a total filtration area equal to or greater than 1 square metre; and
- b. having any of the following characteristics:
 - i. capable of being sterilized or disinfected in-situ; or
 - ii. using disposable or single-use filtration components.

(N.B. This control excludes reverse osmosis equipment, as specified by the manufacturer.)

Cross (tangential) flow filtration components (eg modules, elements, cassettes, cartridges, units or plates) with filtration area equal to or greater than 0.2 square metres for each component and designed for use in cross (tangential) flow filtration equipment as specified above.

Technical note: In this control, 'sterilized' denotes the elimination of all viable microbes from the equipment through the use of either physical (eg steam) or chemical agents. 'Disinfected' denotes the destruction of potential microbial infectivity in the equipment through the use of chemical agents with a germicidal effect. 'Disinfection' and 'sterilization' are distinct from 'sanitization', the latter referring to cleaning procedures designed to lower the microbial content of equipment without necessarily achieving elimination of all microbial infectivity or viability.

5. Freeze-drying Equipment

Steam sterilisable freeze-drying equipment with a condenser capacity of 10 kgs of ice or greater in 24 hours and less than 1000 kgs of ice in 24 hours.

6. Spray-drying Equipment

Spray drying equipment capable of drying toxins or pathogenic microorganisms having all of the following characteristics:

- i. a water evaporation capacity of ≥ 0.4 kg/h and ≤ 400 kg/h
- ii. the ability to generate a typical mean product particle size of ≤ 10 micrometers with existing fittings or by minimal modification of the spray-dryer with atomization nozzles enabling generation of the required particle size; and
- iii. capable of being sterilized or disinfected in situ.

7. Protective and containment equipment as follows:

- a. protective full or half suits, or hoods dependent upon a tethered external air supply and operating under positive pressure;

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

- b. class III 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)).

8. Aerosol inhalation chambers

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

9. Spraying or fogging systems and components therefore, as follows:

- a. Complete spraying or fogging systems, specially designed or modified for fitting to aircraft, lighter than air vehicles or UAVs, capable of delivering, from a liquid suspension, an initial droplet "VMD" of less than 50 microns at a flow rate of greater than two litres per minute.
- b. Spray booms or arrays of aerosol generating units, specially designed or modified for fitting to aircraft, lighter than air vehicles or UAVs, capable of delivering, from a liquid suspension, an initial droplet "VMD" of less than 50 microns at a flow rate of greater than two litres per minute.

- c. Aerosol generating units specially designed for fitting to systems that fulfil all the criteria specified in paragraphs 8.a and 8.b.

Technical Notes

Aerosol generating units are devices specially designed or modified for fitting to aircraft such as nozzles, rotary drum atomisers and similar devices.

This entry does not control spraying or fogging systems and components as specified in paragraph 8 above that are demonstrated not to be capable of delivering biological agents in the form of infectious aerosols.

Pending definition of international standards, the following guidelines should be followed:

Droplet size for spray equipment or nozzles specially designed for use on aircraft or UAVs should be measured using either of the following methods:

- a. Doppler laser method
- b. Forward laser diffraction method

Items for inclusion in Awareness Raising Guidelines

Experts propose that the following items be included in awareness raising guidelines to industry:

1. Equipment for the micro-encapsulation of live micro-organisms and toxins in the range of 1-10 um particle size, specifically:
 - a. interfacial polycondensators;
 - b. phase separators.
2. Fermenters of less than 20 litre 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 P3 or P4 (BL3, BL4, L3, L4) containment facilities.

II. Related Technology

Technology, including licenses, directly associated with

- AG-controlled biological agents; or
- AG-controlled dual-use biological equipment items

to the extent permitted by national legislation.

This includes

- a) transfer of technology (technical data) by any means, including electronic media, fax or telephone
- b) transfer of technology in the form of technical assistance.

Controls on 'technology' do not apply to information 'in the public domain' or to 'basic scientific research' or the minimum necessary information for patent application.

The approval for export of any AG-controlled item of dual-use equipment also authorises the export to the same end-user of the minimum 'technology' required for the installation, operation, maintenance, or repair of that item.

III. SOFTWARE

Controls on 'software' transfer only apply where specifically indicated in sections I and II above, and do not apply to 'software' which is either:

1. Generally available to the public by being:
 - a. Sold from stock at retail selling points without restriction, by means of:
 - i. Over-the-counter transactions;
 - ii. Mail order transactions;
 - iii. Electronic transactions; or
 - iv. Telephone call transactions; and
 - b. Designed for installation by the user without further substantial support by the supplier; or
2. 'In the public domain'.

Definition of Terms

'Basic scientific research'

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.

'Development'

'Development' is related to all stages before production such as:

- assembly of prototypes,
- configuration design,
- design,
- design analysis,
- design concepts,
- design data,
- design research,
- integration design,
- layouts,
- pilot production schemes, and
- process or transforming design data into a product.

'Export'

An actual shipment or transmission of AG-controlled items out of the country. This includes transmission of technology by electronic media, fax or telephone.

'In the public domain'

'In the public domain', as it applies herein, 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.)

'Lighter than air vehicles'

Balloons and airships that rely on hot air or on lighter-than-air gases such as helium or hydrogen for their lift.

'Microprogramme'

A sequence of elementary instructions maintained in a special storage, the execution of which is initiated by the introduction of its reference instruction register.

'Production'

Production means all production phases such as:

- construction,
- production engineering,
- manufacture,
- integration,
- assembly (mounting),
- inspection,
- testing, and
- quality assurance.

'Programme'

A sequence of instructions to carry out a process in, or convertible into, a form executable by an electronic computer.

'Software'

A collection of one or more 'programmes' or 'microprogrammes' fixed in any tangible medium of expression.

'Technical assistance'

May take forms, such as: instruction, skills, training, working knowledge, consulting services. Technical assistance includes oral forms of assistance. Technical assistance may involve transfer of 'technical data'.

'Technical data'

May take forms such as blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals and instructions written or recorded on other media or devices such as disk, tape, read-only memories.

'Technology'

Specific information necessary for the 'development', 'production', or 'use' of a product. The information takes the form of 'technical data' or 'technical assistance'.

'UAVs'

Unmanned Aerial Vehicles.

'Use'

Operation, installation, (including on-site installation), maintenance, (checking), repair, overhaul or refurbishing.

'VMD'

Volume Median Diameter (*note: for water-based systems, VMD equates to MMD – the Mass Median Diameter*).