AUSTRALIA GROUP

CONTROL LIST OF DUAL-USE BIOLOGICAL EQUIPMENT AND RELATED TECHNOLOGY AND SOFTWARE

30 September 2025

I. Equipment

1. Containment facilities and related equipment as follows:

a) 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).

b) Equipment designed for fixed installation in containment facilities specified in a., as follows:

i. Double-door pass-through decontamination autoclaves;

ii. Breathing air suit decontamination showers;

iii. Mechanical-seal or inflatable-seal walkthrough doors.

2. Fermenters

Fermenters capable of cultivation of micro-organisms or of live cells for the production of viruses or toxins, without the propagation of aerosols, having a total internal volume of 20 litres or greater.

Components designed for such fermenters, as follows:

a) cultivation chambers designed to be sterilized or disinfected in situ;

b) cultivation chamber holding devices; or

c) process control units capable of simultaneously monitoring and controlling two or more fermentation system parameters (e.g. temperature, pH, nutrients, agitation, dissolved oxygen, air flow, foam control).

Note 1 – Fermenters include bioreactors (including single-use (disposable) bioreactors), chemostats and continuous-flow systems.

Note 2 - Cultivation chamber holding devices include single-use cultivation chambers with rigid walls.

3. Centrifugal Separators

Centrifugal separators capable of continuous separation, without the propagation of aerosols, having a flow rate greater than 100 litres per hour, as follows:

a) Centrifugal separators having all of the following characteristics:

i. one or more sealing joints within the steam containment area;

ii. components of polished stainless steel or titanium;

iii. capable of in-situ steam sterilisation in a closed state.

b) Single-use centrifugal separators, in which all components that come in direct contact with the substances being processed are disposable or single-use.

Technical note: Centrifugal separators and single-use centrifugal separators include decanters.

4. Cross (tangential) Flow Filtration Equipment

Cross (tangential) flow filtration equipment capable of separation of 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.

(Note - This control excludes equipment designed for reverse osmosis or for filtration of blood for medical applications (e.g. hemodialysis or plasmapheresis), 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 a process to reduce the number of microorganisms but not usually of bacterial spores, through the use of chemical agents, without necessarily killing or removing all organisms.

5. Freeze-drying Equipment

Steam, gas or vapour sterilisable freeze-drying equipment with a condenser capacity of 10 kg of ice or greater in 24 hours and less than 1000 kg 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:

a) a water evaporation capacity of ≥ 0.4 kg/h and ≤ 400 kg/h;

b) 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

c) 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) biocontainment chambers, isolators, or biological safety cabinets having all of the following characteristics, for normal operation:

i. fully enclosed workspace where the operator is separated from the work by a physical barrier;

ii. able to operate at negative pressure;

iii. means to safely manipulate items in the workspace;

iv. supply and exhaust air to and from the workspace is HEPA filtered.

Note 1 - this control includes class III biosafety cabinets, as described in the latest edition of the WHO Laboratory Biosafety Manual or constructed in accordance with national standards, regulations or guidance.

Note 2 - this control includes any isolator meeting all of the above-mentioned characteristics, regardless of its intended use and its designation, except for medical isolators specially designed for barrier nursing or transportation of infected patients.

8. Aerosol inhalation equipment

Aerosol inhalation equipment designed for aerosol challenge testing with micro-organisms, viruses or toxins as follows:

a) Whole-body exposure chambers having a capacity of 1 cubic metre or greater.

b) Nose-only exposure apparatus utilising directed aerosol flow and having capacity for exposure of 12 or more rodents, or 2 or more animals other than rodents; and, closed animal restraint tubes designed for use with such apparatus.

9. Spraying or fogging systems and components therefor, 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 9.a and 9.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*

10. Nucleic acid synthesizers or synthesizers and assemblers

Nucleic acid synthesizers or synthesizers and assemblers, which are partly or entirely automated, and designed to generate continuous nucleic acids greater than 0.5 kilobases in length.

"Software designed for nucleic acid assemblers and synthesizers, controlled above, that is capable of designing and building functional genetic elements from digital sequence data."

11. Peptide synthesizers

Peptide synthesizers that are partly or entirely automated and capable of generating peptides at a 'system synthesis scale' of 1 mmol or greater.

Technical Note: 'System synthesis scale' denotes the maximum amount of peptide (mmol) that can be produced by the instrument using the largest compatible reaction vessels (L). For multiple peptides produced in parallel, this is the sum of the largest compatible reaction vessels (L).

N.B.: See the Control List of Dual-Use Chemical Manufacturing Facilities and Equipment and Related Technology and Software for other chemical reaction vessels or reactors.

Items for inclusion in Awareness Raising Guidelines

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

1. Equipment and technology (not specified elsewhere in the control list of Dual-use Biological Equipment and Related Technology and Software) for the encapsulation of live pathogenic micro-organisms, viruses and toxins, with a typical mean product particle size of 10 □m or less.

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.

4. Agricultural spraying UAVs or drones with a payload of 20 litres or less.

II. Related Technology

'Technology', including licenses, directly associated with:

AG-controlled pathogens and toxins; 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:
>
> design,
> design research,
> design analysis,
> design concepts,
> assembly of prototypes,
> pilot production schemes,
> design data,
> process or transforming design data into a product,
> configuration design,
> integration design, and
> layouts.

‘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’ or ‘software’ that has been made available without restrictions upon its further dissemination. (Copyright restrictions do not remove ‘technology’ or ‘software’ 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.

‘Microprogram’

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

‘Production’

‘Production’ means all production phases such as:

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

‘Program’

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 ‘programs’ or ‘microprograms’ 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)*.