

**Dual-Use Facilities and Equipment related to
the Manufacture of Chemical Weapons and Handling of
Biological Materials Controlled under the Import and Export Ordinance**
(from 17 September 2021)

2B350 Chemical manufacturing facilities, equipment and components, as follows:

- (a) Reaction vessels or reactors, with or without agitators, with total internal (geometric) volume greater than 0.1 m^3 (100 litres) and less than 20 m^3 (20000 litres), where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

N.B.:

For prefabricated repair assemblies, see 2B350(k).

- (1) 'Alloys' with more than 25% nickel and 20% chromium by weight;
- (2) Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);
- (3) Glass (including vitrified or enamelled coating or glass lining);
- (4) Nickel or 'alloys' with more than 40% nickel by weight;
- (5) Tantalum or tantalum 'alloys';
- (6) Titanium or titanium 'alloys';
- (7) Zirconium or zirconium 'alloys';
- (8) Niobium (columbium) or niobium 'alloys';

- (b) Agitators designed for use in reaction vessels or reactors specified in 2B350(a); and impellers, blades or shafts designed for such agitators, where all surfaces of the agitator that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

- (1) 'Alloys' with more than 25% nickel and 20% chromium by weight;
- (2) Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);
- (3) Glass (including vitrified or enamelled coatings or glass lining);
- (4) Nickel or 'alloys' with more than 40% nickel by weight;
- (5) Tantalum or tantalum 'alloys';
- (6) Titanium or titanium 'alloys';
- (7) Zirconium or zirconium 'alloys';
- (8) Niobium (columbium) or niobium 'alloys';

- (c) Storage tanks, containers or receivers with a total internal (geometric) volume greater than 0.1 m^3 (100 litres) where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

N.B.:

For prefabricated repair assemblies, see 2B350(k).

- (1) 'Alloys' with more than 25% nickel and 20% chromium by weight;
- (2) Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);

- (3) Glass (including vitrified or enamelled coatings or glass lining);
- (4) Nickel or 'alloys' with more than 40% nickel by weight;
- (5) Tantalum or tantalum 'alloys';
- (6) Titanium or titanium 'alloys';
- (7) Zirconium or zirconium 'alloys';
- (8) Niobium (columbium) or niobium 'alloys';
- (d) Heat exchangers or condensers with a heat transfer surface area greater than 0.15 m², and less than 20 m²; and tubes, plates, coils or blocks (cores) designed for such heat exchangers or condensers, where all surfaces that come in direct contact with the chemical(s) being processed are made from any of the following materials:
 - (1) 'Alloys' with more than 25% nickel and 20% chromium by weight;
 - (2) Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);
 - (3) Glass (including vitrified or enamelled coatings or glass lining);
 - (4) Graphite or 'carbon graphite';
 - (5) Nickel or 'alloys' with more than 40% nickel by weight;
 - (6) Tantalum or tantalum 'alloys';
 - (7) Titanium or titanium 'alloys';
 - (8) Zirconium or zirconium 'alloys';
 - (9) Silicon carbide;
 - (10) Titanium carbide;
 - (11) Niobium (columbium) or niobium 'alloys';
- (e) Distillation or absorption columns of internal diameter greater than 0.1 m; and liquid distributors, vapour distributors or liquid collectors designed for such distillation or absorption columns, where all surfaces that come in direct contact with the chemical(s) being processed are made from any of the following materials:
 - (1) 'Alloys' with more than 25% nickel and 20% chromium by weight;
 - (2) Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);
 - (3) Glass (including vitrified or enamelled coatings or glass lining);
 - (4) Graphite or 'carbon graphite';
 - (5) Nickel or 'alloys' with more than 40% nickel by weight;
 - (6) Tantalum or tantalum 'alloys';
 - (7) Titanium or titanium 'alloys';
 - (8) Zirconium or zirconium 'alloys';
 - (9) Niobium (columbium) or niobium 'alloys';
- (f) Remotely operated filling equipment in which all surfaces that come in direct contact with the chemical(s) being processed are made from any of the following materials:
 - (1) 'Alloys' with more than 25% nickel and 20% chromium by weight; or
 - (2) Nickel or 'alloys' with more than 40% nickel by weight;
- (g) Valves and components, as follows:

- (1) Valves that meet all of the following descriptions:
 - (a) A 'nominal size' greater than 10 mm (3/8");
 - (b) All surfaces that come in direct contact with the chemical(s) being produced, processed, or contained are made from 'corrosion resistant materials';
- (2) Valves, other than those specified in 2B350(g)(1), that meet all of the following descriptions:
 - (a) A 'nominal size' equal to or greater than 25.4 mm (1") and equal to or less than 101.6 mm (4");
 - (b) Casings (valve bodies) or preformed casing liners;
 - (c) A closure element designed to be interchangeable;
 - (d) All surfaces of the casing (valve body) or preformed casing liner that come in direct contact with the chemical(s) being produced, processed, or contained are made from 'corrosion resistant materials';
- (3) Components, designed for valves specified in 2B350(g)(1) or 2B350(g)(2), in which all surfaces that come in direct contact with the chemical(s) being produced, processed, or contained are made from 'corrosion resistant materials', as follows:
 - (a) Casings (valve bodies);
 - (b) Preformed casing liners;

Technical Notes:

1. For the purposes of 2B350(g), 'corrosion resistant materials' mean any of the following materials:
 - (a) Nickel or 'alloys' with more than 40% nickel by weight;
 - (b) 'Alloys' with more than 25% nickel and 20% chromium by weight;
 - (c) Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);
 - (d) Glass or glass-lined (including vitrified or enamelled coating);
 - (e) Tantalum or tantalum 'alloys';
 - (f) Titanium or titanium 'alloys';
 - (g) Zirconium or zirconium 'alloys';
 - (h) Niobium (columbium) or niobium 'alloys';
 - (i) Ceramic materials as follows:
 - (1) Silicon carbide with a purity of 80% or more by weight;
 - (2) Aluminium oxide (alumina) with a purity of 99.9% or more by weight;
 - (3) Zirconium oxide (zirconia).
 2. 'Nominal size' is defined as the smaller of the inlet and outlet diameters.
- (h) Multi-walled piping incorporating a leak detection port, in which all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

- (1) 'Alloys' with more than 25% nickel and 20% chromium by weight;
 - (2) Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);
 - (3) Glass (including vitrified or enamelled coatings or glass lining);
 - (4) Graphite or 'carbon graphite';
 - (5) Nickel or 'alloys' with more than 40% nickel by weight;
 - (6) Tantalum or tantalum 'alloys';
 - (7) Titanium or titanium 'alloys';
 - (8) Zirconium or zirconium 'alloys';
 - (9) Niobium (columbium) or niobium 'alloys';
- (i) Multiple-seal and seal-less pumps with manufacturer's specified maximum flow-rate greater than 0.6 m³/hour, or vacuum pumps with manufacturer's specified maximum flow-rate greater than 5 m³/hour (under standard temperature (273 K (0°C)) and pressure (101.3 kPa) conditions, other than those specified in 2B233); and casings (pump bodies), preformed casing liners, impellers, rotors or jet pump nozzles designed for such pumps, in which all surfaces that come in direct contact with the chemical(s) being processed are made from any of the following materials:
- (1) Alloys with more than 25% nickel and 20% chromium by weight;
 - (2) Ceramics;
 - (3) Ferrosilicon (high silicon iron 'alloys');
 - (4) Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);
 - (5) Glass (including vitrified or enamelled coatings or glass lining);
 - (6) Graphite or 'carbon graphite';
 - (7) Nickel or 'alloys' with more than 40% nickel by weight;
 - (8) Tantalum or tantalum 'alloys';
 - (9) Titanium or titanium 'alloys';
 - (10) Zirconium or zirconium 'alloys';
 - (11) Niobium (columbium) or niobium 'alloys';

Technical Note:

In 2B350(i), the term seal refers to only those seals that come into direct contact with the chemical(s) being processed (or is designed to), and provide a sealing function where a rotary or reciprocating drive shaft passes through a pump body.

- (j) Incinerators designed to destroy chemicals controlled by 1C350, having specially designed waste supply systems, special handling facilities and an average combustion chamber temperature greater than 1273 K (1000°C), in which all surfaces in the waste supply system that come into direct contact with the waste products are made from or lined with any of the following materials:
- (1) 'Alloys' with more than 25% nickel and 20% chromium by weight;
 - (2) Ceramics; or
 - (3) Nickel or 'alloys' with more than 40% nickel by weight;

(k) Prefabricated repair assemblies having metallic surfaces that come in direct contact with the chemical(s) being processed that are made from tantalum or tantalum alloys as follows, and specially designed components for such prefabricated repair assemblies:

- (1) Designed for mechanical attachment to glass-lined reaction vessels or reactors specified in 2B350(a); or
- (2) Designed for mechanical attachment to glass-lined storage tanks, containers or receivers specified in 2B350(c);

Note:

For the purposes of 2B350, the materials used for gaskets, packing, seals, screws, washers or other materials performing a sealing function do not determine the status of control, provided that such components are designed to be interchangeable.

Technical Note:

1. 'Carbon graphite' is a composition of amorphous carbon and graphite, in which the graphite content is 8% or more by weight.
2. For the listed materials in the above entries, the term 'alloy' when not accompanied by a specific elemental concentration is understood as identifying those alloys where the identified metal is present in a higher percentage by weight than any other element.

2B351 Toxic gas monitors and monitoring systems, and their dedicated detecting components, other than those specified in 1A004, as follows; and detectors; sensor devices; and replaceable sensor cartridges:

- (a) Designed for continuous operation and usable for the detection of chemical warfare agents or chemicals controlled by 1C350, at concentrations of less than 0.3 mg/m³; or
- (b) Designed for the detection of cholinesterase-inhibiting activity;

2B352 Biological manufacturing and handling equipment, as follows:

- (a) Containment facilities and related equipment as follows:
 - (1) 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);
 - (2) Equipment designed for fixed installation in containment facilities specified in 2B352(a), as follows:
 - (a) Double-door pass-through decontamination autoclaves;
 - (b) Breathing air suit decontamination showers;
 - (c) Mechanical-seal or inflatable-seal walkthrough doors;
- (b) Fermenters and components as follows:
 - (1) 'Fermenters' capable of cultivation of "microorganisms" or of live cells for the production of viruses or toxins, without the propagation of aerosols, and having a total capacity of 20 litres or more;
 - (2) Components designed for 'fermenters' in 2B352(b)(1) as follows:

- (a) Cultivation chambers designed to be sterilized or disinfected in situ;
- (b) Cultivation chamber holding devices;
- (c) Process control units capable of simultaneously monitoring and controlling 2 or more fermentation system parameters (e.g. temperature, pH, nutrients, agitation, dissolved oxygen, air flow, foam control);

Technical Note:

For the purposes of 2B352(b), 'fermenters' include bioreactors, single-use (disposable) bioreactors, chemostats and continuous-flow systems.

- (c) Centrifugal separators, capable of continuous separation without the propagation of aerosols, having all the following characteristics:
 - (1) Flow rate exceeding 100 litres per hour;
 - (2) Components of polished stainless steel or titanium;
 - (3) One or more sealing joints within the steam containment area; and
 - (4) Capable of in-situ steam sterilisation in a closed state;

Technical Note:

Centrifugal separators include decanters.

- (d) Cross (tangential) flow filtration equipment and component as follows:
 - (1) Cross (tangential) flow filtration equipment capable of separation of "microorganisms", viruses, "toxins" or cell cultures, that meets all of the following descriptions:
 - (a) A total filtration area equal to or greater than 1 m²; *and*
 - (b) Meeting any of the following descriptions:
 - (1) Capable of being 'sterilised' or 'disinfected' in-situ;
 - (2) Using disposable or single-use filtration components;

Technical Note:

In 2B352(d)(1)(b), 'sterilised' denotes the elimination of all viable microbes from the equipment through the use of either physical (e.g. 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 sterilisation 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.

- (2) Cross (tangential) flow filtration components (e.g. modules, elements, cassettes, cartridges, units or plates) with filtration area equal to or greater than 0.2 m² for each component and designed for use in cross (tangential) flow filtration equipment controlled by 2B352(d);

Note:

2B352(d) does not control reverse osmosis equipment and hemodialysis equipment, as specified by the manufacturer.

- (e) Steam, gas or vapour sterilisable freeze drying equipment with a condenser capacity of 10 kg of ice or more in 24 hours and less than 1000 kg of ice in 24 hours;
- (f) Protective and containment equipment, as follows:
 - (1) Protective full or half suits, or hoods dependent upon a tethered external air supply and operating under positive pressure;

Note:

2B352(f)(1) does not control suits designed to be worn with self-contained breathing apparatus.

- (2) Biocontainment chambers, isolators, or biological safety cabinets having all of the following characteristics, for normal operation:
 - (a) Fully enclosed workspace where the operator is separated from the work by a physical barrier;
 - (b) Able to operate at negative pressure;
 - (c) Means to safely manipulate items in the workspace;
 - (d) Supply and exhaust air to and from the workspace is HEPA filtered;

Note:

- 1. 2B352(f)(2) 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.
- 2. 2B352(f)(2) does not include isolators specially designed for barrier nursing or transportation of infected patients.

- (g) Aerosol inhalation equipment designed for aerosol challenge testing with “microorganisms”, viruses or “toxins” as follows:
 - (1) Whole-body exposure chambers having a capacity of 1 m³ or more;
 - (2) Nose-only exposure apparatus utilizing directed aerosol flow and having capacity for exposure of any of the following:
 - (a) 12 or more rodents;
 - (b) 2 or more animals other than rodents;
 - (3) Closed animal restraint tubes designed for use with nose-only exposure apparatus utilizing directed aerosol flow;
- (h) Spray-drying equipment capable of drying “toxins” or pathogenic “microorganisms”, that meets all of the following descriptions:
 - (1) Having a water evaporation capacity of ≥ 0.4 kg/h and ≤ 400 kg/h;
 - (2) Having the ability to generate a typical mean product particle size of ≤ 10 μm with existing fittings or by minimal modification of the spray-dryer with atomization nozzles enabling generation of the required particle size;
 - (3) Capable of being ‘sterilized’ or ‘disinfected’ in situ;

- (i) Nucleic acid assemblers and synthesisers, which are partly or entirely automated, and designed to generate continuous nucleic acids greater than 1.5 kilobases in length with error rates less than 5% in a single run;

9A350 Spraying or fogging systems, specially designed or modified for fitting to “aircraft”, “lighter-than-air vehicles” or “unmanned aerial vehicles” controlled by 9A012, and specially designed components therefor, as follows:

- (a) Complete spraying or fogging systems capable of delivering, from a liquid suspension, an initial droplet the ‘VMD’ of which is less than 50 microns at a flow rate of greater than two litres per minute;
- (b) Spray booms or arrays of ‘aerosol generating units’ capable of delivering, from a liquid suspension, an initial droplet the ‘VMD’ of which is 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 controlled by 9A350(a) and 9A350(b);

Notes:

1. ‘Aerosol generating units’ are devices specially designed or modified for fitting to “aircraft” such as nozzles, rotary drum atomizers and similar devices.
2. 9A350 does not control spraying or fogging systems and components that are demonstrated not to be capable of delivering “biological agents” in the form of infectious aerosols.

Technical Notes:

1. Droplet size for spray equipment or nozzles specially designed for use on “aircraft”, “lighter-than-air vehicles” or “unmanned aerial vehicles” controlled by 9A012 should be measured using either of the following:
 - (a) Doppler laser method;
 - (b) Forward laser diffraction method.
2. In 9A350, ‘VMD’ means Volume Median Diameter and, for water-based system, this equates to Mass Median Diameter (MMD).

Remarks: The products list is for reference only and may be subject to change from time to time. Traders are advised to refer to the schedules promulgated in the Import and Export (Strategic Commodities) Regulations (Cap. 60G) for up-to-date information in relation to scope of products subject to licensing requirements.