

CHAPTER 2 – REQUIREMENTS OF CERTIFICATION

This Chapter is divided into two Parts:

General requirements (Part 1) outlines the requirements that must be complied with by the holder of any certification for a facility, irrespective of the type of facility and the containment level to which the facility is certified; and

Specific requirements (Part 2) outlines the specific requirements that must be complied with for facilities certified to varying containment levels.

PART 1: GENERAL REQUIREMENTS

The holder of the certification must:

- maintain control of GMO dealings in the facility through processes appropriate to the facility's containment level and type;
- prevent release of GMOs and organisms infected with GMOs from the facility unless specifically approved (in writing) by the Regulator;
- prevent the persistence of GMOs and organisms infected with GMOs within the facility other than those being stored or used in a dealing;
- comply, and ensure all people in the facility comply with, the Specific Conditions identified in Part 2 which apply to the facility, as specified in the Regulator's instrument of certification under section 84 of the Act; and
- ensure that the facility is inspected at least once per year. A copy of the inspection report must detail the extent of compliance with the Regulator's conditions of certification and must be provided to the Regulator if requested. Any non-compliance issues must be notified to the Regulator as soon as practicable.

2. REQUIREMENTS FOR A PHYSICAL CONTAINMENT LEVEL 2 (PC2) PLANT CONTAINMENT FACILITY

General

- 1 The work that can be conducted in a facility that is certified as a Physical Containment Level 2 (PC2) Plant Containment Facility includes work with GM plants, and/or plants infected with GMOs, that present a low to moderate potential risk to people and/or the environment.

Facilities

- 2^{*} The facility must be labelled with the following adhesive signs as supplied by the OGTR:
 - (a) a Physical Containment Level 2 (PC2) sign on the outside of the facility door(s) or the anteroom door(s);
 - (b) a biohazard symbol on the outside of facility access door(s) or the anteroom door(s); and
 - (c) a PC2 Facility Practice sign prominently displayed inside the facility.
- 3^{*} The facility must be a fully enclosable, fixed structure with walls, a roof and a floor. Planhouses must have lockable doors and must be designed to prevent the entry of surface run-off water. The ground surrounding the facility must be kept free of plants (e.g. by paving the area or laying down gravel and using a herbicide regime).
- 4 The transparent sections of a planhouse must be made of glass, polycarbonate sheeting, or other similar durable material. It is not permitted to use flimsy materials, such as shade cloth or thin film plastic sheeting, or a combination of flimsy materials, as the only outer cladding of transparent sections. Transparent sections must be impact resistant or protected from impact.
- 5 The facility must have an anteroom. Entry to the facility must be through the anteroom, unless entry is through another containment facility certified by the Regulator to PC2. Emergency exits must not be used except in emergencies. The anteroom must be fitted with a system to kill arthropods (e.g. sticky pest strip, automatic insecticide aerosol dispenser or high voltage electrical insect trap).
- 6^{*} The insides of the walls and roof, and the benches must be impermeable to water and resistant to the cleaning agents and/or disinfectants used in the facility. Facility furniture, including seating, must be washable.
- 7 The floors of the facility must be made of concrete or some alternative durable, impervious material.

^{*} OGTR requirement additional to AS/NZS 2243.3:2002

- 8 Any openings in the walls, ceiling or roof must be screened with fine mesh screens having apertures of 0.56 mm and a wire diameter of 0.28 mm. The mesh must be of a material mechanically strong enough to withstand the airflow load, remain undamaged with regular cleaning, resist corrosion and resist attack by insects.
- 9 If the facility has drainage exits, they must be fitted with wire mesh to prevent entry of rodents and insects. Where the work of the facility involves GM micro-organisms the drains must be also be fitted with disinfectant traps or the run off must be contained (prevented from entering the drains) and treated as waste.
- 10 A wash basin must be provided, either in the anteroom or inside the facility. Where the entry to the Plant Containment Facility is through another containment facility certified by the Regulator to PC2, the wash basin may be located in the adjoining certified PC2 facility.
- 11^{*} Designated storage or hanging provisions for protective clothing must be available within the facility or the anteroom.
- 12^{*} A supply of disinfectants for decontamination purposes must be available in the facility if the work of the facility involves GM micro-organisms. The disinfectants must be clearly labelled with the contents and, where necessary, the expiry date.
- 13^{*} Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.

Personal protective clothing and equipment

- 14^{*} Protective clothing (e.g.. laboratory coats or overalls) must be worn by all persons performing procedures in the facility.
- 15^{*} Protective clothing must be removed before leaving the facility. This may be in the anteroom. This requirement does not apply if entering another containment facility, certified by the Regulator to PC2, that is directly connected to the facility.

Work practices

- 16^{*} All requirements for a PC2 Plant Containment Facility specified in the Certification Instrument issued by the Regulator must be complied with at all times, even if the work being performed in the facility involves organisms that are not GMOs.
- 17 Access to the facility must be restricted to authorised persons and/or authorised classes of persons.
- 18 All facility personnel must be trained in the requirements of the OGTR PC2 Plant Containment Facility Guidelines. Only trained personnel are to clean contaminated equipment and surfaces, or handle waste that contains GM micro-organisms or material capable of regenerating GMOs.
- 19^{*} Facility personnel must indicate to the certification holder that they fully understand their training in the OGTR requirements by signing a record of their training after completion. A record of those trained must be kept and made available if requested.

- 20^{*} Any unintentional release of GMOs from the facility must be reported to the Regulator as soon as practicable.
- 21^{*} Work benches, surfaces and equipment, where procedures involving GM micro-organisms have taken place, must be decontaminated immediately after any spills, and when procedures using GM micro-organisms are completed. Work benches, surfaces and equipment that have collected material capable of regenerating GMOs must be cleaned regularly.
- 22^{*} All surfaces and equipment, in relevant areas of the facility, that may contain GM micro-organisms or material capable of regenerating GMOs, must be decontaminated before maintenance is carried out.
- 23^{*} Plants infected with GMOs, and material potentially contaminated with GM micro-organisms or containing reproductive material of GM plants (including soil and other growth media, waste resulting from a GMO dealing, and equipment), must be rendered biologically inactive by one of the following methods before disposal:
- (a) pressure steam sterilisation (autoclaving);
 - (b) super heated (non-pressurised) steam; or
 - (c) any other method approved in writing by the Regulator,
- unless being disposed of via incineration.
- Incineration must be in a high temperature, high efficiency, EPA-approved incineration facility.
- 24^{*} GM plants, micro-organisms and any reproductive material of GM plants that would survive treatment by non-pressurised super heated steam as per paragraph 23 , must be killed by one of the following methods before disposal:
- (a) pressure steam sterilisation (autoclaving); or
 - (b) any other method approved in writing by the Regulator,
- unless being disposed of via incineration.
- Incineration must be in a high temperature, high efficiency EPA-approved incineration facility.
- 25 Where a pressure steam steriliser (autoclave) is used for decontamination:
- (a) Provision must be made to allow for the penetration of steam into the container during autoclaving.
 - (b) The coldest part of the load must be exposed to a minimum temperature of 121 C for at least 15 minutes.
 - (c) Measures must be taken to ensure that loads that have been processed can be differentiated from loads that have not (e.g. autoclave tape).

- (d) The temperature of each cycle must be monitored by use of one of the following means: a thermocouple and recorder; a maximum thermometer; a chemical indicator; spore strips; or readings from the autoclave panel.
 - (e) The effectiveness of decontamination by the pressure steam steriliser (autoclave) used by the facility must be tested monthly with biological indicators. A notice must be posted on, or adjacent to, the autoclave indicating the result and the date of the latest test.
- 26^{*} Where superheated, non-pressurised, steam is used for decontamination
- (a) Provision must be made to allow for the penetration of steam into the load.
 - (b) The coldest part of the load must be exposed to a minimum temperature of 98° C for at least 2 hours, or a minimum temperature and time approved in writing by the Regulator.
 - (c) Measures must be taken to ensure that loads that have been processed can be differentiated from loads that have not.
 - (d) Thermocouples must be used to record temperatures.
 - (e) Thermocouples must be calibrated to ensure that they indicate the correct temperature. The intervals between calibrations should be sufficiently frequent to provide confidence that routine cycles of the steam steriliser achieve the desired temperature. Records of such calibrations must be kept for inspection for at least 12 months.
- 27^{*} All GMOs, and waste potentially contaminated with GMOs, being transported out of the facility must be transported in accordance with the "*Guidelines for the Transport of GMOs*".
- 28^{*} Animals and plants not used in the work being performed in the facility must be regarded as waste on removal from the facility and decontaminated in accordance with paragraph 23.
- 29^{*} Viable plant material must not be removed from the facility unless:
- (a) it is to be transported to a containment facility certified by the Regulator to equivalent or higher containment level; or
 - (b) it is to be transported to another location for disposal or treatment prior to disposal; or
 - (c) it is to be transported to another site for a release subject to a licence for a Dealing Involving the Intentional Release of a GMO into the environment (DIR); or
 - (d) written permission has been given by the Regulator for an exemption to this requirement in respect of non-GM plants kept in growth cabinets, that have been clearly labelled, in facilities where no GM micro-organisms have been used and where there has been no possibility of cross-contamination or cross-fertilisation.

Viable plant material, except where exempted in (d) must be transported in accordance with the "*Guidelines for the Transport of GMOs*".

- 30^{*} GMOs or organisms infected with GMOs may be stored outside the facility in a storage unit (freezer, fridge, controlled temperature room or other controlled temperature container). The storage unit must be locked when not in use, unless access is restricted to the room or area where the storage unit is located, and have a biohazard symbol posted on it.
- 31^{*} GMOs or organisms infected with GMOs being stored outside the facility must be double-contained. The primary container must be sealed and unbreakable. The primary container must be stored in an unbreakable secondary container and clearly labelled. In the case of a small storage unit such as a fridge, freezer or liquid nitrogen container, the secondary container may be the storage unit.
- 32^{*} Transport of material between the facility and the storage unit must be in accordance with the "*Guidelines for the Transport of GMOs*". Gloves must be worn while transferring primary containers between the storage unit and the secondary container used for transport. Any spills that occur during storage outside the facility or when transferring to the storage unit must be reported to the Regulator as soon as practicable. The spilt material and the area must be decontaminated.
- 33^{*} Eating, drinking, smoking, shaving and applying cosmetics are prohibited in the facility. Food or drink intended for human consumption must not be brought into or stored in the facility.
- 34 Hands must be washed with soap and water before leaving the facility.
- 35^{*} The facility and equipment in the facility must be maintained so that the facility meets the containment requirements of these Guidelines.
- 36 Regular inspections of the facility, including plants, soils and other growth media, for the presence of invertebrate pests and for any unwanted micro-organisms, must be undertaken.
- 37 When unwanted infestations are identified treatment of the facility is required to eradicate the infestation. A record of unwanted organisms detected, treatments to remove them and the dates of the treatments, must be kept and made available if requested.