Schedule 2 Dealings exempt from licensing

(regulation 6)

Note Subregulation 6 (1) sets out other requirements for exempt dealings.

Part 1 Exempt dealings

Item	Description of dealing
2	A dealing with a genetically modified *Caenorhabditis elegans*, unless: (a) an *advantage* is conferred on the animal by the genetic modification; or (b) as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent.
3	A dealing with an animal into which genetically modified somatic cells have been introduced, if: (a) the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; and (b) the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.
3A	A dealing with an animal whose somatic cells have been genetically modified *in vivo* by a replication defective viral vector, if: (a) the *in vivo* modification occurred as part of a previous dealing; and (b) the replication defective viral vector is no longer in the animal; and (c) no germ line cells have been genetically modified; and (d) the somatic cells cannot give rise to infectious agents as a result of the genetic modification; and (e) the animal is not infected with a virus that can recombine with the genetically modified nucleic acid in the somatic cells of the animal.
4	(1) Subject to subitem (2), a dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 25 litres of GMO culture in each vessel containing the resultant culture.

Item	Description of dealing
	(2) The donor nucleic acid: (a) must meet either of the following requirements: (i) it must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy: (A) human beings; or (B) animals; or (C) plants; or (D) fungi; (ii) it must be characterised and the information derived from its characterisation show that it is unlikely to increase the capacity of the host or vector to cause harm; *Example* Donor nucleic acid would not comply with subparagraph (ii) if its characterisation shows that, in relation to the capacity of the host or vector to cause harm, it: (a) provides an advantage; or (b) adds a potential host species or mode of transmission; or (c) increases its virulence, pathogenicity or transmissibility; and (b) must not code for a toxin with an LD_{50} of less than 100 μg/kg; and (c) must not code for a toxin with an LD_{50} of 100 μg/kg or more, if the intention is to express the toxin at high levels; and (d) must not be uncharacterised nucleic acid from a toxin-producing organism; and (e) must not include a viral sequence, unless the donor nucleic acid: (i) is missing at least 1 gene essential for viral multiplication that: (A) is not available in the cell into which the nucleic acid is introduced; and (B) will not become available during the dealing; and (ii) cannot restore replication competence to the vector.
5	A dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in item 1 of Part 2 of this Schedule, if the donor nucleic acid is not derived from either: (a) a pathogen; or (b) a toxin-producing organism.