



## 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 <i>Caenorhabditis elegans</i> , unless: (a) an <i>advantage</i> 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 <i>in vivo</i> by a replication defective viral vector, if: (a) the <i>in vivo</i> 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)	<p>The donor nucleic acid:</p> <ul style="list-style-type: none"> <li>(a) must meet either of the following requirements: <ul style="list-style-type: none"> <li>(i) it must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy: <ul style="list-style-type: none"> <li>(A) human beings; or</li> <li>(B) animals; or</li> <li>(C) plants; or</li> <li>(D) fungi;</li> </ul> </li> <li>(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;</li> </ul> </li> </ul>
	<p><i>Example</i></p> <p>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:</p>
	<ul style="list-style-type: none"> <li>(a) provides an advantage; or</li> <li>(b) adds a potential host species or mode of transmission; or</li> <li>(c) increases its virulence, pathogenicity or transmissibility; and</li> </ul>
	<ul style="list-style-type: none"> <li>(b) must not code for a toxin with an LD<sub>50</sub> of less than 100 µg/kg; and</li> </ul>
	<ul style="list-style-type: none"> <li>(c) must not code for a toxin with an LD<sub>50</sub> of 100 µg/kg or more, if the intention is to express the toxin at high levels; and</li> </ul>
	<ul style="list-style-type: none"> <li>(d) must not be uncharacterised nucleic acid from a toxin-producing organism; and</li> </ul>
	<ul style="list-style-type: none"> <li>(e) must not include a viral sequence, unless the donor nucleic acid:</li> </ul>
	<ul style="list-style-type: none"> <li>(i) is missing at least 1 gene essential for viral multiplication that:</li> </ul>
	<ul style="list-style-type: none"> <li>(A) is not available in the cell into which the nucleic acid is introduced; and</li> </ul>
	<ul style="list-style-type: none"> <li>(B) will not become available during the dealing; and</li> </ul>
	<ul style="list-style-type: none"> <li>(ii) cannot restore replication competence to the vector.</li> </ul>
5	<p>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:</p> <ul style="list-style-type: none"> <li>(a) a pathogen; or</li> <li>(b) a toxin-producing organism.</li> </ul>