



Types of dealings with GMOs classified as Exempt Dealings

Part 1 of Schedule 2 of the Gene Technology Regulations 2001 (the Regulations) describes the type of dealings which are classified as exempt. Part 2 of Schedule 2 determines the host/vector systems relevant to Item 4 of Part 1. These host/vector systems are also relevant to the classification of Notifiable Low Risk Dealings (NLRDs) and Dealings not involving Intentional Release (DNIR) in Schedule 3 of the Regulations. Part 3 provides definitions of terms used in this Schedule.

Below is an excerpt from the Regulations incorporating amendments from Schedule 1 of the Gene Technology Amendment (2019 Measures No. 1) Regulations 2019, **which commence on 8 October 2019**.

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. (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:

Item	Description of dealing
	<ul style="list-style-type: none"> (A) human beings; or (B) animals; or (C) plants; or (D) fungi; <p>(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; and</p> <p>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:</p> <ul style="list-style-type: none"> (a) provides an advantage; or (b) adds a potential host species or mode of transmission; or (c) increases its virulence, pathogenicity or transmissibility. <p>(b) must not code for a toxin with an LD₅₀ of less than 100 micrograms per kilogram; and</p> <p>(c) must not code for a toxin with an LD₅₀ of 100 micrograms per kilogram or more, if the intention is to express the toxin at high levels; and</p> <p>(d) must not be uncharacterised nucleic acid from a toxin-producing organism; and</p> <p>(e) if the donor nucleic acid includes a viral sequence—cannot give rise to infectious agents when introduced into any potential host species, without additional non-host genes or gene products that:</p> <ul style="list-style-type: none"> (i) are not available in the host cell into which the nucleic acid is introduced as part of the dealing; and (ii) will not become available during the dealing; and <p>(f) if the donor nucleic acid includes a viral sequence—cannot restore replication competence to the vector.</p>
5	<p>A dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in items 1 to 6 of the table in Part 2 of this Schedule, if the donor nucleic acid is not derived from either:</p> <ul style="list-style-type: none"> (a) a pathogen; or (b) a toxin-producing organism.

Part 2—Host/vector systems for exempt dealings

2.1 Hosts and vectors

- (1) A reference to a host mentioned in this Part is a reference to a host mentioned in column 2 of an item of the table in this clause.
- (2) A reference to a vector mentioned in this Part is a reference to a vector mentioned in column 3 of an item of the table in this clause.
- (3) A reference to a **host/vector system** mentioned in this Part is a reference to any of the following:
 - (a) a system involving a host mentioned in column 2 of an item of the table in this clause and a vector mentioned in column 3 of the same item;
 - (b) a non-vector system involving a host mentioned in column 2 of an item of the table;
 - (c) a system involving a GMO mentioned as a vector in column 3 of an item of the table (except item 7), without a host.

Note: Column 1 of the table is included for information only.

Hosts and vectors			
Item	Column 1 Host class	Column 2 Hosts	Column 3 Vectors
1	Bacteria	<i>Escherichia coli</i> K12, <i>E. coli</i> B, <i>E. coli</i> C or <i>E. coli</i> Nissle 1917—any derivative that does not contain: (a) generalised transducing phages; or (b) genes able to complement the conjugation defect in a non-conjugative plasmid	Any of the following: (a) non-conjugative plasmids; (b) lambda bacteriophage; (c) lambdoid bacteriophage; (d) Fd, F1 or M13 bacteriophage
2	Bacteria	<i>Bacillus</i> —asporogenic strains of the following species with a reversion frequency of less than 10^{-7} : (a) <i>B. amyloliquefaciens</i> ; (b) <i>B. licheniformis</i> ; (c) <i>B. pumilus</i> ; (d) <i>B. subtilis</i> ; (e) <i>B. thuringiensis</i>	Any of the following: (a) non-conjugative plasmids; (b) other plasmids and phages whose host range does not include <i>B. cereus</i> , <i>B. anthracis</i> or any other pathogenic strain of <i>Bacillus</i>
3	Bacteria	<i>Pseudomonas putida</i> strain KT2440	Non-conjugative plasmids
4	Bacteria	The following <i>Streptomyces</i> species: (a) <i>S. aureofaciens</i> ; (b) <i>S. coelicolor</i> ; (c) <i>S. cyaneus</i> ; (d) <i>S. griseus</i> ; (e) <i>S. lividans</i> ; (f) <i>S. parvulus</i> ; (g) <i>S. rimosus</i> ; (h) <i>S. venezuelae</i>	Any of the following: (a) non-conjugative plasmids; (b) plasmids SCP2, SLP1, SLP2, pIJ101 and derivatives; (c) actinophage phi C31 and derivatives
5	Bacteria	Any of the following: (a) <i>Agrobacterium radiobacter</i> ; (b) <i>Agrobacterium rhizogenes</i> (disarmed strains only); (c) <i>Agrobacterium tumefaciens</i> (disarmed strains only)	Disarmed Ri or Ti plasmids

Hosts and vectors			
Item	Column 1 Host class	Column 2 Hosts	Column 3 Vectors
6	Bacteria	Any of the following: (a) <i>Allorhizobium</i> species; (b) <i>Corynebacterium glutamicum</i> ; (c) <i>Lactobacillus</i> species; (d) <i>Lactococcus lactis</i> ; (e) <i>Oenococcus oeni</i> syn. <i>Leuconostoc oeni</i> ; (f) <i>Pediococcus</i> species; (g) <i>Photobacterium angustum</i> ; (h) <i>Pseudoalteromonas tunicata</i> ; (i) <i>Rhizobium</i> species; (j) <i>Sphingopyxis alaskensis</i> syn. <i>Sphingomonas alaskensis</i> ; (k) <i>Streptococcus thermophilus</i> ; (l) <i>Synechococcus</i> species strains PCC 7002, PCC 7942 and WH 8102; (m) <i>Synechocystis</i> species strain PCC 6803; (n) <i>Vibrio cholerae</i> CVD103-HgR; (o) <i>Zymomonas mobilis</i>	Non-conjugative plasmids
7	Fungi	Any of the following: (a) <i>Kluyveromyces lactis</i> ; (b) <i>Neurospora crassa</i> (laboratory strains); (c) <i>Pichia pastoris</i> ; (d) <i>Saccharomyces cerevisiae</i> ; (e) <i>Schizosaccharomyces pombe</i> ; (f) <i>Trichoderma reesei</i> ; (g) <i>Yarrowia lipolytica</i>	All vectors
8	Slime moulds	<i>Dictyostelium</i> species	<i>Dictyostelium</i> shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2
9	Tissue culture	Any of the following if they cannot spontaneously generate a whole animal: (a) animal or human cell cultures (including packaging cell lines); (b) isolated cells, isolated tissues or isolated organs, whether animal or human; (c) early non-human mammalian embryos cultured <i>in vitro</i>	Any of the following: (a) plasmids; (b) replication defective viral vectors unable to transduce human cells; (c) polyhedrin minus forms of the baculovirus <i>Autographa californica</i> nuclear polyhedrosis virus (ACNPV)
10	Tissue culture	Either of the following if they are not intended, and are not likely without human intervention, to vegetatively propagate, flower or regenerate into a whole plant: (a) plant cell cultures; (b) isolated plant tissues or organs	Any of the following: (a) Disarmed Ri or Ti plasmids in <i>Agrobacterium radiobacter</i> , <i>Agrobacterium rhizogenes</i> (disarmed strains only) or <i>Agrobacterium tumefaciens</i> (disarmed strains only); (b) non-pathogenic viral vectors

Part 3—Definitions

In this Schedule:

code for, in relation to a toxin, means to specify the amino acid sequence of the toxin.

non-conjugative plasmid means a plasmid that is not self-transmissible, and includes, but is not limited to, non-conjugative forms of the following plasmids:

- (a) bacterial artificial chromosomes (BACs);
- (b) cosmids;
- (c) P1 artificial chromosomes (PACs);
- (d) yeast artificial chromosomes (YACs).

non-vector system means a system in which donor nucleic acid is or was introduced into a host cell:

- (a) in the absence of a nucleic acid-based vector; or
- (b) using a nucleic acid-based vector in the course of a previous dealing and the vector is:
 - (i) no longer present; or
 - (ii) present but cannot be remobilised from a host cell.

Example 1: A system mentioned in paragraph (a) might involve the use of electroporation or particle bombardment.

Example 2: A system mentioned in paragraph (b) might involve cells that were transduced with a replication defective retroviral vector in which no vector particles remain.