



WHAT DEALINGS WITH GMOs ARE CLASSIFIED AS EXEMPT DEALINGS?

Excerpt from the **Gene Technology Regulations 2001 (Statutory Rules 2001 No. 106 as amended)** (the Regulations), effective from 1 September 2011

Part 1 of Schedule 2 of the Regulations describes the type of dealings with are classified as exempt. Part 2 of Schedule 2 determines the host/vector system 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.

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.

Item	Description of dealing
4	<p>(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.</p> <p>(2) The donor nucleic acid:</p> <p>(a) must meet either of the following requirements:</p> <p>(i) it must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy:</p> <p>(A) human beings; or</p> <p>(B) animals; or</p> <p>(C) plants; or</p> <p>(D) fungi;</p> <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;</p> <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> <p>(a) provides an advantage; or</p> <p>(b) adds a potential host species or mode of transmission; or</p> <p>(c) increases its virulence, pathogenicity or transmissibility; and</p> <p>(b) must not code for a toxin with an LD₅₀ of less than 100 µg/kg; and</p> <p>(c) must not code for a toxin with an LD₅₀ of 100 µg/kg 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) must not include a viral sequence, unless the donor nucleic acid:</p> <p>(i) is missing at least 1 gene essential for viral multiplication that:</p> <p>(A) is not available in the cell into which the nucleic acid is introduced; and</p> <p>(B) will not become available during the dealing; and</p> <p>(ii) 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 item 1 of Part 2 of this Schedule, if the donor nucleic acid is not derived from either:</p> <p>(a) a pathogen; or</p> <p>(b) a toxin-producing organism.</p>

Part 2 Host/vector systems for exempt dealings

Item	Class	Host	Vector
1	Bacteria	<p><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:</p> <p>(a) generalised transducing phages; or</p> <p>(b) genes able to complement the conjugation defect in a non-conjugative plasmid</p> <p><i>Bacillus</i> — specified species — asporogenic strains with a reversion frequency of less than 10^{-7}:</p> <p>(a) <i>B. amyloliquefaciens</i></p> <p>(b) <i>B. licheniformis</i></p> <p>(c) <i>B. pumilus</i></p> <p>(d) <i>B. subtilis</i></p> <p>(e) <i>B. thuringiensis</i></p> <p><i>Pseudomonas putida</i> — strain KT 2440</p> <p><i>Streptomyces</i> — specified species:</p> <p>(a) <i>S. aureofaciens</i></p> <p>(b) <i>S. coelicolor</i></p> <p>(c) <i>S. cyaneus</i></p> <p>(d) <i>S. griseus</i></p> <p>(e) <i>S. lividans</i></p> <p>(f) <i>S. parvulus</i></p> <p>(g) <i>S. rimosus</i></p> <p>(h) <i>S. venezuelae</i></p> <p><i>Agrobacterium radiobacter</i></p> <p><i>Agrobacterium rhizogenes</i> — disarmed strains</p> <p><i>Agrobacterium tumefaciens</i> — disarmed strains</p>	<p>1. Non-conjugative plasmids</p> <p>2. Bacteriophage</p> <p>(a) lambda</p> <p>(b) lambdoid</p> <p>(c) Fd or F1 (eg M13)</p> <p>3. None (non-vector systems)</p> <p>1. Non-conjugative plasmids</p> <p>2. 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></p> <p>3. None (non-vector systems)</p> <p>1. Non-conjugative plasmids including certified plasmids: pKT 262, pKT 263, pKT 264</p> <p>2. None (non-vector systems)</p> <p>1. Non-conjugative plasmids</p> <p>2. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives</p> <p>3. Actinophage phi C31 and derivatives</p> <p>4. None (non-vector systems)</p> <p>1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors</p> <p>2. None (non-vector systems)</p>

Item	Class	Host	Vector
		<i>Lactobacillus</i>	1. Non-conjugative plasmids
		<i>Lactococcus lactis</i>	2. None (non-vector systems)
		<i>Oenococcus oeni</i> syn. <i>Leuconostoc oeni</i>	
		<i>Pediococcus</i>	
		<i>Photobacterium angustum</i>	
		<i>Pseudoalteromonas tunicata</i>	
		<i>Rhizobium</i> (including the genus <i>Allorhizobium</i>)	
		<i>Sphingopyxis alaskensis</i> syn. <i>Sphingomonas alaskensis</i>	
		<i>Streptococcus thermophilus</i>	
		<i>Synechococcus</i> — specified strains:	
		(a) PCC 7002	
		(b) PCC 7942	
		(c) WH 8102	
		<i>Synechocystis</i> species — strain PCC 6803	
		<i>Vibrio cholerae</i> CVD103-HgR	
2	Fungi	<i>Kluyveromyces lactis</i>	1. All vectors
		<i>Neurospora crassa</i> — laboratory strains	2. None (non-vector systems)
		<i>Pichia pastoris</i>	
		<i>Saccharomyces cerevisiae</i>	
		<i>Schizosaccharomyces pombe</i>	
		<i>Trichoderma reesei</i>	
		<i>Yarrowia lipolytica</i>	
3	Slime moulds	<i>Dictyostelium</i> species	1. <i>Dictyostelium</i> shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2
			2. None (non-vector systems)
4	Tissue culture	Any of the following if they cannot spontaneously generate a whole animal:	1. Non-conjugative plasmids
		(a) animal or human cell cultures (including packaging cell lines);	2. Non-viral vectors, or replication defective viral vectors unable to transduce human cells
		(b) isolated cells, isolated tissues or isolated organs, whether animal or human;	3. Baculovirus (<i>Autographa californica</i> nuclear polyhedrosis virus), polyhedrin minus
		(c) early non-human mammalian embryos cultured <i>in vitro</i>	4. None (non-vector systems)

Item	Class	Host	Vector
		<p>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:</p> <p>(a) plant cell cultures;</p> <p>(b) isolated plant tissues or organs</p>	<p>1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in <i>Agrobacterium tumefaciens</i>, <i>Agrobacterium radiobacter</i> or <i>Agrobacterium rhizogenes</i></p> <p>2. Non-pathogenic viral vectors</p> <p>3. None (non-vector systems)</p>

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.