



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)

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.
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 10 litres of GMO culture in each vessel containing the resultant culture. (2) The donor nucleic acid: (a) must satisfy either of the following requirements: (i) it must not be derived from organisms implicated in, or with a history of causing, disease in human beings, animals, plants or fungi; or (ii) it must be characterised and not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector; and

Item	Description of dealing
	<ul style="list-style-type: none"> (b) must not code for a toxin with an LD₅₀ of less than 100 µg/kg; and (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 (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: <ul style="list-style-type: none"> (i) is missing at least 1 gene essential for viral multiplication that: <ul style="list-style-type: none"> (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) is incapable of correcting a defect in the host/vector system leading to production of replication competent virions; and (f) must not confer an oncogenic modification.
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"> (a) a pathogen; or (b) a toxin-producing organism.

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 or <i>E. coli</i> C – any derivative that does not contain:</p> <ul style="list-style-type: none"> (a) generalised transducing phages; or (b) genes able to complement the conjugation defect in a non-conjugative plasmid 	<ul style="list-style-type: none"> 1. Non-conjugative plasmids 2. Bacteriophage <ul style="list-style-type: none"> (a) lambda (b) lambdoid (c) Fd or F1 (eg M13) 3. None (non-vector systems)

Item	Class	Host	Vector
		Bacillus – specified species – asporogenic strains with a reversion frequency of less than 10 ⁻⁷ :	1. Non-conjugative plasmids
		(a) <i>B. amyloliquefaciens</i>	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>
		(b) <i>B. licheniformis</i>	
		(c) <i>B. pumilus</i>	
		(d) <i>B. subtilis</i>	
		(e) <i>B. thuringiensis</i>	3. None (non-vector systems)
		<i>Pseudomonas putida</i> – strain KT 2440	1. Non-conjugative plasmids including certified plasmids: pKT 262, pKT 263, pKT 264
			2. None (non-vector systems)
		Streptomyces – specified species:	1. Non-conjugative plasmids
		(a) <i>S. aureofaciens</i>	2. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives
		(b) <i>S. coelicolor</i>	
		(c) <i>S. cyaneus</i>	
		(d) <i>S. griseus</i>	3. Actinophage phi C31 and derivatives
		(e) <i>S. lividans</i>	
		(f) <i>S. parvulus</i>	4. None (non-vector systems)
		(g) <i>S. rimosus</i>	
		(h) <i>S. venezuelae</i>	
		<i>Agrobacterium radiobacter</i>	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors
		<i>Agrobacterium rhizogenes</i> — disarmed strains	
		<i>Agrobacterium tumefaciens</i> — disarmed strains	2. None (non-vector systems)
		<i>Lactobacillus</i>	1. Non-conjugative plasmids
		<i>Oenococcus oeni</i> syn.	
		<i>Leuconostoc oeni</i>	2. None (non-vector systems)

Item	Class	Host	Vector
		<i>Pediococcus</i>	systems)
		<i>Photobacterium angustum</i>	
		<i>Pseudoalteromonas tunicate</i>	
		<i>Rhizobium</i> (including the genus <i>Allorhizobium</i>)	
		<i>Sphingopyxis alaskensis</i> syn. <i>Sphingomonas alaskensis</i>	
		<i>Vibrio cholerae</i> CVD103-HgR	
2	Fungi	<i>Neurospora crassa</i> – laboratory strains	1. All vectors
		<i>Pichia pastoris</i>	2. None (non-vector systems)
		<i>Saccharomyces cerevisiae</i>	
		<i>Schizosaccharomyces pombe</i>	
		<i>Kluyveromyces lactis</i>	
		<i>Trichoderma reesei</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	Animal or human cell cultures (including packaging cell lines)	1. Non-conjugative plasmids
			2. Non-viral vectors, or defective viral vectors unable to transduce human cells
			3. Avipox vectors (attenuated vaccine strains)

Item	Class	Host	Vector
			4. Baculovirus (<i>Autographa californica</i> nuclear polyhedrosis virus), polyhedrin minus
			5. None (non-vector systems)
		Plant cell cultures	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>
			2. Non-pathogenic viral vectors
			3. None (non-vector systems)

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 by which donor nucleic acid is introduced (for example, by electroporation or particle bombardment) into a host in the absence of a nucleic acid-based vector (for example, a plasmid, viral vector or transposon).