

The purpose of this table is to provide guidance to help in the identification of which schedules to review in the Regulations by providing a high-level overview of some of the common dealings and conditions. **Please note that each dealing has highly specific conditions listed within the Regulations that must be read in full to determine the correct classification.**

	Example parent organism/vector combinations. (review the linked schedules for full conditions)	Examples of common conditions (review the linked schedules for full conditions)	Schedules to review
<b>Exempt Dealings</b>	<ul style="list-style-type: none"> <li>• <i>Caenorhabditis elegans</i>;</li> <li>• An animal into which genetically modified somatic cells have previously been introduced;</li> <li>• An animal whose somatic cells have previously been genetically modified <i>in vivo</i> by a replication defective viral vector;</li> <li>• Isolated cells, tissues or organs derived from GMO animals or plants</li> <li>• Parent organism/vector combinations in the exempt host/vector list at the back of this document.</li> <li>• Shotgun cloning or preparation of cDNA library in exempt hosts from Items 1-6 in list at the end of this document.</li> </ul>	<ul style="list-style-type: none"> <li>• Cannot give rise to infectious agents (for animals and <i>C. elegans</i>).</li> <li>• <i>C. elegans</i> must not have a genetic advantage because of the modification.</li> <li>• Animals cannot be infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.</li> <li>• Animals must not have germ line cells genetically modified.</li> </ul> <p>For exempt parent organisms/vectors from the list at the back of this document:</p> <ul style="list-style-type: none"> <li>• Donor nucleic acid either must <u>not</u> be derived from a pathogen, or it must be characterised and shown to be unlikely to increase the capacity of the parent organism or vector to cause harm.</li> <li>• Donor nucleic acid must <u>not</u> encode a toxin, and must <u>not</u> be uncharacterised nucleic acid from a toxin producing organism.</li> <li>• If the donor nucleic acid contains a viral sequence, it cannot be capable of producing a virus when introduced into any host species, and it cannot restore replication competence to a viral vector.</li> <li>• Less than 25 litres of GMO culture per vessel.</li> </ul>	<a href="#">Schedule 2, Part 1</a>

	Example parent organism/vector combinations. (review the linked schedules for full conditions)	Examples of common conditions (review the linked schedules for full conditions)	Schedules to review
<b>Notifiable Low Risk Dealings (NLRD)</b>	<ul style="list-style-type: none"> <li>Laboratory guinea pig, mouse, rabbit or rat with no genetic advantage (PC1)</li> <li><i>In vitro</i> dealings with replication defective Human adenovirus or adeno-associated virus (PC1)</li> <li>Animals other than laboratory guinea pig, mouse, rabbit, rat or <i>C. elegans</i> (PC2)</li> <li>Laboratory guinea pig, mouse, rabbit, rat or <i>C. elegans</i> with a genetic advantage (PC2)</li> <li>Whole plants (PC2)</li> <li>Risk group 2 microorganisms (PC2)</li> <li>Complementation studies (PC2)</li> <li>Shotgun cloning or cDNA libraries in non-exempt hosts (PC2)</li> <li>Exempt hosts with non-exempt modifications (PC2)</li> <li>Non-exempt hosts (PC2)</li> <li><i>In vitro</i> and <i>in vivo</i> dealings with replication defective viral vectors, including non-retroviral, lentiviral and retroviral vectors (PC2).</li> <li>Risk group 3 microorganisms (PC3)</li> </ul>	<p>Conditions vary depending on the type of dealing undertaken. Please read the relevant schedules in full to determine if your work meets the conditions, and contact the IBC for assistance (<a href="mailto:ibc@adelaide.edu.au">ibc@adelaide.edu.au</a>).</p> <p>All viral vectors must be replication defective. For some (e.g., retroviral vectors) the method of achieving this is specified in the conditions.</p> <p>Excludes genetic modifications that confer toxin production.</p> <p>Excludes gene drive modifications.</p> <p>Generally excludes work that may increase the pathogenicity or virulence of the host.</p> <p>Excludes <i>in vivo</i> dealings with viral vectors that are able to transduce human cells, if the dealing involves immunomodulatory or oncogenic modifications.</p> <p>As the University does not operate a PC2 large scale facility, cannot undertake dealings producing more than 25 litres of GMO culture per vessel.</p> <p>Please note that the University does not operate PC3 facilities, and therefore dealings requiring this level of containment cannot be endorsed.</p>	<p>PC1 NLRD – <a href="#">Schedule 3, Part 1, 1.1</a></p> <p>PC2 NLRD – <a href="#">Schedule 3, Part 2, 2.1</a></p> <p>PC3 NLRD – <a href="#">Schedule 3, Part 2, 2.2</a></p>

	<b>Example parent organism/vector combinations.</b> (review the linked schedules for full conditions)	<b>Examples of common conditions</b> (review the linked schedules for full conditions)	Schedules to review
<b>DIR licence</b>	<p>Work involving the release of GMOs into the environment. Typically this will include field trials of GM plants.</p> <p>May also include some clinical or veterinary trials occurring outside of containment facilities, for example, where the GMO may be shed from the host.</p>	<p>These applications result in a licence from the OGTR which will specify the relevant conditions.</p> <p>Before preparing a DIR licence, please contact the IBC for discussion of your requirements.</p>	
<b>DNIR licence</b>	<p>Any host/vector combination where the conditions for exempt or NLRD dealings are not met.</p> <p>Some clinical or veterinary trials occurring outside of containment facilities, for example, where the GMO remains contained or is not shed from the host.</p>	<p>DNIR conditions can vary outside of what is listed in the Regulations. If you are undertaking a dealing that does not clearly fit within the scope of an exempt or notifiable low risk dealing, but is being undertaken in containment, it will likely fall within the DNIR category.</p> <p>Before preparing a DNIR licence, please contact the IBC for discussion of your requirements.</p> <p>Please note that the University does not operate PC3 or PC4 facilities, and therefore dealings requiring this level of containment cannot be endorsed by the IBC or OGTR.</p>	<a href="#">Schedule 3, Part 3</a>

**Exempt Parent Organism/Vector Combinations (with conditions – refer to [Schedule 2, Part 1, Item 4](#)).**

**Parent Organisms and vectors**

- (1) A reference to a host (parent organism) 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 (parent organism) 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.

**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);	Disarmed Ri or Ti plasmids

## Hosts and vectors

Item	Column 1 Host class	Column 2 Hosts	Column 3 Vectors
		(c) <i>Agrobacterium tumefaciens</i> (disarmed strains only)	
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	Any of the following:

## Hosts and vectors

Item	Column 1 Host class	Column 2 Hosts	Column 3 Vectors
		human intervention, to vegetatively propagate, flower or regenerate into a whole plant: (a) plant cell cultures; (b) isolated plant tissues or organs	(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

## Definitions

**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.