APPLICATION FOR AN EXEMPT DEALING

Please attach Risk Assessments, plasmid maps and / or manuals pertinent to the GMO for which you are making application to the IBC.

1. **Project Title**

   <Project Title>

2. **Project Supervisor**

   <Name of Project Supervisor>

   School: <Details of School and campus>
   Building and Room No.: <Building and room No.>
   Phone: <Work phone number>
   Email: <work email address>

3. **Project Dates** (please note a project must not begin before the IBC has given approval)

   Commencement Date: dd/mm/yy

   Finishing Date: dd/mm/yy

4. **Exemption Category** (please mark applicable category with an x)

   **refer to table at end of this form for the detailed description of each category.*

1-2	Dealing with a genetically modified *Caenorhabditis elegans*	
1-3	Dealing with an animal into which genetically modified somatic cells have been introduced	
1-3A	Dealing with an animal whose somatic cells have been genetically modified in vivo by a replication defective viral vector	
1-4	Dealing involving a host / vector system	
	HOST / VECTOR DETAILS Item: Class: Host: Vector:	
1-5	Dealing involving a shotgun cloning OR the preparation of a cDNA library, in a host / vector system	

4.1 Modified trait(s) – class and details

<response>.

4.2 Details of recombinant DNA, including vector

<response, including brief summary of procedures if relevant>.

5. PC Level:

6. Facilities to be used

Facility Name:

Building No.

Room No.

7. Method of Waste Disposal:

<Description of proposed method of disposal>.

8. Principal Investigator:

<Name of Principal Investigator>

....

Signature Date

*Categories of Dealings Exempt from Licensing under the Gene Technology Regulations 2001, effective from 1 September 2011

PART 1 EXEMPT DEALINGS

Item	Description of dealing
1-2	A dealing with a genetically modified *Caenorhabditis elegans*, unless: a. an *advantage* 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.
1-3	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.
1-3A	A dealing with an animal whose somatic cells have been genetically modified *in vivo* by a replication defective viral vector, if a. the *in vivo* 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
1-4	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: (a) human beings; or (b) animals; or (c) plants; or (d) fungi; 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 *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: (a) provides an advantage; or (b) adds a potential host species or mode of transmission; or (c) increases its virulence, pathogenicity or transmissibility; and b. must not code for a toxin with an $LD_{50}$of less than 100 microg/kg; and c. must not code for a toxin with an LD_{50} of 100 microg/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: i. is missing at least 1 gene essential for viral multiplication that (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. cannot restore replication competence to the vector.
1-5	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: a. a pathogen; or b. a toxin-producing organism

PART 2 HOST/VECTOR SYSTEMS FOR EXEMPT DEALINGS

Item	Class	Host	Vector
2-1	Bacteria	*Escherichia coli* K12, *E. coli* B , *E. coli* C or *E. coli* 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	1. Non-conjugative plasmids 2. Bacteriophage (a) lambda (b) lambdoid (c) Fd or F1 (eg M13) 3. None (non-vector systems)
		Bacillus — specified species — asporogenic strains with a reversion frequency of less than 10^{-7}: a. *B. amyloliquefaciens* b. *B. licheniformis* c. *B. pumilus* d. *B. subtilis* e. *B. thuringiensis*	1. Non-conjugative plasmids 2. Plasmids and phages whose host range does not include *B. cereus*, *B. anthracis* or any other pathogenic strain of *Bacillus* 3. None (non-vector systems)
		Pseudomonas putida — strain KT 2440	1. Non-conjugative plasmids including certified plasmids: pKT 262, pKT 263, pKT 264 2. None (non-vector systems
		Streptomyces — specified species: a. *S. aureofaciens* b. *S. coelicolor* c. *S. cyaneus* d. *S. griseus* e. *S. lividans* f. *S. parvulus* g. *S. rimosus* h. *S. venezuelae*	1. Non-conjugative plasmids 2. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives 3. Actinophage phi C31 and derivatives 4. None (non-vector systems)
		Agrobacterium radiobacter *Agrobacterium rhizogenes* — disarmed strains *Agrobacterium tumefaciens* — disarmed strains	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors 2. None (non-vector systems)
		Lactobacillus *Lactococcus lactis* *Oenococcus oeni* syn. *Leuconostoc oeni* *Pediococcus* *Photobacterium angustum* *Pseudoalteromonas tunicata* *Rhizobium* (including the genus *Allorhizobium*) *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis* *Streptococcus thermophilus* *Synechococcus* — specified strains: (a) PCC 7002 (b) PCC 7942 (c) WH 8102	1. Non-conjugative plasmids 2. None (non-vector systems)

Item	Class	Host	Vector
		Synechocystis species — strain PCC 6803 *Vibrio cholerae* CVD103-HgR	
2-2	Fungi	*Kluyveromyces lactis* *Neurospora crassa* — laboratory strains *Pichia pastoris* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe* *Trichoderma reesei* *Yarrowia lipolytica*	1. All vectors 2. None (non-vector systems)
2-3	Slime moulds	*Dictyostelium* species	1. *Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 2. None (non-vector systems)
2-4	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 *in vitro*	1. Non-conjugative plasmids 2. Non-viral vectors, or replication defective viral vectors unable to transduce human cells 3. Baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedrin minus 4. None (non-vector systems)
		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	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in *Agrobacterium tumefaciens*, *Agrobacterium radiobacter* or *Agrobacterium rhizogenes* 2. Non-pathogenic viral vectors 3. None (non-vector systems)