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UNIVERSITY
OF WOLLONGONG
AUSTRALIA

Sample

Notification of an Exempt Dealing

COVER SHEET

Project Title:	Cloning and expression of cadmium resistance genes in *E. coli* *(Please clearly indicate the nature of the GMO dealing, rather than giving just a general research project title)*
Project Supervisor:	
Faculty/Unit:	
Telephone No:	Fax No:
Anticipated Start Date:	Completion Date:
Room(s) where GMO will be used, including containment level:	
Room(s) where GMO is stored:	
Other Universities and/or facilities to be involved in the research:	

GTRC Declaration
The GTRC has evaluated this dealing and agrees that it is an exempt dealing as specified by Schedule 2 of the *Gene Technology Regulations 2001* and the *Gene Technology Amendment Regulations 2011*.

Signature of Project Supervisor: …… Date: ……

Signature of
Head of Unit: ……... Date: ……

Signature of
Chair of GTRC:…… Date: ……

Date of GTRC Approval:

LIST OF RESEARCHERS INVOLVED IN THE PROJECT

Please list the names of all staff and students who will be participating in the project, and give details of their training. Before working with GMOs each person listed below must complete the online Biosafety and GMO Training Course and satisfactorily pass the GMO Quiz. The quiz can be accessed on Moodle at: https://moodle.uowplatform.edu.au/course/view.php?id=11362. The enrolment key is 'Biosafety'.

Please note the following:

- Each person must also have completed a local induction to the laboratory in question and be listed as an authorised user for the laboratory.
- The project supervisor should be an academic employed at UOW and her/his tenure should cover the duration of project, otherwise such an academic staff member should be nominated as co-supervisor and secondary contact.

	Name	**Position**	GMO Quiz Completed? Yes/No
Principal Investigator (Project Supervisor)	_____	_____	_____
Co-Investigator	_____ _____ _____	_____ _____ _____	_____ _____ _____
Other Participants	_____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____

Gene Technology Review Committee

1	**Project Summary - briefly describe the project, including the aims of the proposed dealing, method of producing GMOs (if applicable) and their use. Please justify why this project is an Exempt Dealing based on the criteria including those for host/vector system and donor nucleic acids (this should be written in plain English).**

Sample

Aim and Background: To identify and characterise bacterial genes responsible for cadmium resistance. Cadmium (Cd) contamination is a global problem. Identification of the genes responsible for such resistance will not only advance our knowledge of Cd resistance at molecular level but may also help develop novel approach to solving the contamination problem.

Description of GMO Dealing: We will use the shot-gun method to clone large DNA fragments of *Bacillus* sp. CDB isolated from a contaminated site (xxxx et al. 2007) in *E. coli* to screen for Cd resistance clones on Cd-containing media. Putative resistance proteins will then be produced using expression vectors in *E. coli* for function investigation. Recombinant DNA will be introduced into *E. coli* using standard chemical heat-shock or electroporation transformation methods.

Justification of Dealing Level:
Donor nucleic acids - From *Bacillus* sp. CDB, not known as pathogen to other organisms. Host – *E. coli* B12 strains such as JM109 and M15.
Vectors – Common *E. coli* cloning vectors such as pGEM7(+) and expression vector such as pQE30. None of them is conjugative.
The dealing will be contained in the PC1 facilities listed above producing no more than 25 litres of GMO culture in each vessel containing the resultant culture. The GMOs generated will not be intentionally released into the environment.

Ref……

2	**Exemption Category – Highlight the items that apply**

Schedule 2 Dealings exempt from licensing

Part 1 Exempt dealings

Item	Description of dealing
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.
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 *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

Item	Description of dealing
	(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: (A) human beings; or (B) animals; or (C) plants; or (D) fungi; (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; *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 μg/kg; and (c) must not code for a toxin with an LD_{50} 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: (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.
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.

3 Circle the host/vector system that will be used

Part 2 Host/vector systems for exempt dealings

Item	Class	Host	Vector
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)

Item	Class	Host	Vector
		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 *Synechocystis* species — strain PCC 6803 *Vibrio cholerae* CVD103-HgR	1. Non-conjugative plasmids 2. None (non-vector systems)

Item	Class	Host	Vector
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)
3	Slime moulds	*Dictyostelium* species	1. *Dictyostelium* 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: (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)