*This application form should be completed for Exempt Dealings as categorised in the Commonwealth Gene Technology Regulations 2001 and in the Gene Technology Amendment (2019 Measures No. 1) Regulations 2019. Completed applications should be submitted electronically to the Biosafety Officer:* *ibcadmin@flinders.edu.au**.*

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| **OFFICE USE ONLY** | **Application ID** |  |
| **Date of IBC approval** |  |
| **Approval expiry date** |  |
| **Dealing type** |  |

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| 1 | General Information |
| Project Title:**(to be reported to OGTR)** |       |
| **Organisation(s) where the dealing will be conducted (name all applicable)** |       |
| **Has this dealing been approved by or is currently being reviewed by another IBC?**  | [ ]  Yes [ ]  No *If yes, please submit relevant approval notice and record of assessment and complete following details* |
| **Other IBC name** |       |
| **Dealing ID**  |       |
| **Does this application replace another approved dealing?** | [ ]  Yes [ ]  No *If yes, complete following details* |
| **Dealing ID** |       |
| **Name of the approving IBC** |       |
| **Category of dealing** | [ ]  Exempt[ ]  PC1 NLRD [ ]  PC2 NLRD[ ]  DNIR |
| 1.1 | Project Supervisor / Chief Investigator Details |
| **Name** |       |
| **Organisation/ Employer**  |       |
| **Telephone** |       |
| **Email address** |       |
| **Has the Project Supervisor/ Chief Investigator previously submitted an application to this IBC?** | [ ]  Yes [ ]  No *If no, please provide a brief outline below of relevant experience and qualifications in relation to GMO work*       |
| 1.2 | Preferred Contact Person details |
| **Same as above** | [ ]  |
| **Preferred Contact Person** |       |
| **Organisation/ Employer**  |       |
| **Telephone** |       |
| **Email address** |       |
| **Has the Preferred Contact Person previously submitted a dealing application to this IBC?** | [ ]  Yes [ ]  No *If no, please provide a brief outline below of relevant experience and qualifications in relation to GMO work*       |

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| **2 Lay Summary** - please include a short summary of the project using lay language |
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| 3 | About the dealing |
| **Proposed commencement date** |  |
| **3.1 Description of the dealing** |
| *Only dealings that are listed on an approval notice can be undertaken. Therefore, please ‘check’ the dealings that will be undertaken.**NOTE: A dealing includes the possession, supply or use of the GMO, for the purposes of, or in the course of, a dealing mentioned in any of activities listed.**\*As defined in the Gene Technology Act 2000: thing, includes a substance, and a thing in electronic or magnetic form.* | [ ]  Conduct experiments with the GMO |
| [ ]  Make, develop, produce or manufacture the GMO |
| [ ]  Breed the GMO |
| [ ]  Propagate the GMO |
| [ ]  Use the GMO in the course of manufacture of a thing\* that is not the GMO*If yes, complete following details*Is the thing\* subject to regulation by other agencies (e.g. Food Standards Australia, Australian Pesticides and Veterinary Medicines Association, Therapeutic Goods Administration)[ ]  Yes ⮚ Agency      [ ]  No |
| [ ]  Grow, raise or culture the GMO |
| [ ]  Import the GMO*If yes, complete following details*Is an Import Permit required? Search BICON for further information: <https://bicon.agriculture.gov.au/BiconWeb4.0/> [ ]  Yes ⮚ DAWR Import Permit ID      [ ]  No |
| [ ]  Transport the GMO |
| [ ]  Dispose of the GMO**IF SELECTED, PLEASE IDENTIFY DISPOSAL METHOD:**[ ]  Solid Waste - Disposal via biohazard waste stream[ ]  Solid Waste - Autoclaving prior to disposal via biohazard waste[ ]  Solid Waste - Chemical disinfection prior to disposal via biohazard waste[ ]  Liquid Waste - Chemical disinfection prior to disposal via sewerage system[ ]  Liquid Waste - Autoclaving prior to disposal via sewerage system[ ]  Liquid Waste - Small volumes (< 50 mL) sealed in enclosed vessel and disposed of via biohazard waste stream[ ]  Other – describe:       |
| [ ]  Store the GMO |
| Does this dealing involve:[ ]  Human Ethics Committee approval ⮚ Approval no:       or [ ]  pending [ ]  Animal Ethics Committee approval ⮚ Approval no:       or [ ]  pending [ ]  Radiation[ ]  Carcinogenic / hazardous substances[ ]  Security Sensitive Biological Agents[ ]  Import of biological materials from an overseas locationIf YES please see [**Appendix 1**](#_APPENDIX_2_–) for further instructions. |

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| 4 | Exempt dealing types  |
| Refer to the Schedules in the Gene Technology Regulations 2001, available online at [**https://www.legislation.gov.au/Details/F2019C00781**](https://www.legislation.gov.au/Details/F2019C00781) to determine the correct type(s) of dealing(s). Indicate all that apply. |
| [ ]  **Schedule 2, Part 1, Item 2 – a dealing with genetically modified *Caenorhabditis elegans******If Schedule 2, Part 1, Item 2 is selected, please answer 4.1 and 4.2 below:*** **4.1 – Is any genetic advantage conferred on the *C. elegans* by the genetic modification?** [ ]  Yes [ ]  No**4.2 – Is the *C. elegans* capable of secreting or producing an infectious agent because of the genetic modification?**[ ]  Yes [ ]  NoPLEASE NOTE: If yes is selected for questions 4.1 or 4.2, this is not an exempt dealing. Please complete an NLRD or licenced dealing application. For assistance determining the dealing type, please contact the IBC (ibcadmin@flinders.edu.au).  |
| [ ]  **Schedule 2, Part 1, Item 3 – a dealing with an animal into which genetically modified somatic cells have been introduced*****If Schedule 2, Part 1, Item 3 is selected, please answer 4.3, 4.4 and 4.5 below:*** **4.3 – Please describe the genetic modification to the somatic cells. If the cells are derived from another IBC approved dealing, please provide the corresponding IBC approval number.**      **4.4 – Are the genetically modified somatic cells capable of giving rise to infectious agents because of the genetic modification?**[ ]  Yes [ ]  NoPLEASE NOTE: If yes is selected for 4.4, this is not an exempt dealing. Please complete an NLRD or licenced dealing application. For assistance determining the dealing type, please contact the IBC (ibcadmin@flinders.edu.au).**4.5 – Is the animal into which the somatic cells are being introduced knowingly infected with a virus (including any known natural infection)?**[ ]  Yes [ ]  No***4.5.1 - If yes is selected at 4.5 – please describe the virus, addressing whether or not there is any possibility that the virus is capable of recombining with the genetically modified nucleic acid in the somatic cells.***       |
| [ ]  **Schedule 2, Part 1, Item 3A – a dealing with an animal whose somatic cells have been genetically modified *in vivo* by a replication defective viral vector*****If Schedule 2, Part 1, Item 3A is selected, please answer 4.6 – 4.10 below:*** **4.6 – Did the *in vivo* modification occur as part of a previous dealing?** [ ]  Yes [ ]  No**4.7 – Is there any expectation that the replication defective viral vector may still be present in the animal?**[ ]  Yes [ ]  No**4.8 – Have any germ line cells been genetically modified in the animal?** [ ]  Yes [ ]  No**4.9 – Are the genetically modified somatic cells capable of giving rise to infectious agents as a result of the genetic modification?** [ ]  Yes [ ]  NoPLEASE NOTE: If yes is selected for questions 4.6, 4.7, 4.8 or 4.9, this is not an exempt dealing. Please complete an NLRD or licenced dealing application. For assistance determining the dealing type, please contact the IBC (ibcadmin@flinders.edu.au).**4.10 – Is the animal knowingly infected with a virus (including any known natural infection)?**[ ]  Yes [ ]  No***4.10.1 - If yes is selected at 4.5 – please describe the virus, addressing whether or not there is any possibility that the virus is capable of recombining with the genetically modified nucleic acid in the somatic cells.***       |
| [ ]  **Schedule 2, Part 1, Item 4 – a dealing involving a host/vector system in Part 2 of Schedule 2 and producing no more than 25 L of GMO culture in each vessel containing the resultant culture.** ***If Schedule 2, Part 1, Item 4 is selected, please answer 4.11-4.13 below:*** **4.11 – Which of the following conditions do the donor nucleic acids meet?** Select all that apply[ ]  The donor nucleic acids are not derived from an organism implicated in, or with a history of causing, disease in otherwise healthy humans, animals, plants, or fungi. [ ]  The donor nucleic acids are fully characterised, and the information derived from their characterisation shows that they are unlikely to increase the capacity of the host or vector to cause harm. NB: Donor nucleic acid would not comply with the above option if its characterisation shows that, in relation to the capacity of the host or vector to cause harm, it: provides an advantage; adds a potential host species or mode of transmission; increases virulence, pathogenicity or transmissibility.[ ]  Neither - PLEASE NOTE: this is not an exempt dealing. Please complete an NLRD or licenced dealing application. For assistance determining the dealing type, please contact the IBC (ibcadmin@flinders.edu.au).**4.12 – Does the donor nucleic acid come from a toxin-producing organism?** [ ]  Yes [ ]  No***4.12.1 – If yes is selected at 4.12: Is the donor nucleic acid uncharacterised?*** [ ]  Yes [ ]  No***4.12.2 – If yes is selected at 4.12: Does the donor nucleic acid code for a toxin with an LD50 of more than 100µg/kg?*** [ ]  Yes [ ]  NoPLEASE NOTE: If yes is selected for questions 4.12.1 or 4.12.2, this is not an exempt dealing. Please complete an NLRD or licenced dealing application. For assistance determining the dealing type, please contact the IBC (ibcadmin@flinders.edu.au).**4.13 – Does the donor nucleic acid include a viral sequence?** [ ]  Yes [ ]  No***4.13.1 – If yes is selected at 4.13: Describe the viral sequence/s provided by the donor nucleic acid***     ***4.13.2 – If yes is selected at 4.13: Do the viral sequence/s include genes that would normally be essential for viral multiplication?***[ ]  Yes [ ]  No***4.13.3 – If yes is selected at 4.13: Can viral multiplication be restored by introduction into the proposed host, or through activities associated with the proposed dealing?*** [ ]  Yes [ ]  No***4.13.4 – If yes is selected at 4.13: Can the viral sequence restore replication competence to the vector?*** [ ]  Yes [ ]  NoPLEASE NOTE: If yes is selected for questions 4.13.2, 14.3.3, or 4.13.4, this is not an exempt dealing. Please complete an NLRD or licenced dealing application. For assistance determining the dealing type, please contact the IBC (ibcadmin@flinders.edu.au). |
| [ ]  **Schedule 2, Part 1, Item 5 – a dealing involving shotgun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in Items 1 to 6 of Schedule 2, Part 2.** ***If Schedule 2, Part 1, Item 5 is selected, please answer 4.14 and 4.15 below:*** **4.14 – Is the donor nucleic acid derived from a pathogen?** [ ]  Yes [ ]  No**4.15 – Is the donor nucleic acid derived from a toxin-producing organism?** [ ]  Yes [ ]  NoPLEASE NOTE: If yes is selected for questions 4.14 or 4.15, this is not an exempt dealing. Please complete an NLRD or licenced dealing application. For assistance determining the dealing type, please contact the IBC (ibcadmin@flinders.edu.au). |

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| 5 | About the host/vector system(s) |
| **5.1 Please select all hosts and vectors that apply from the list below** |
| Item | Class | Host (select all that apply) | Vector (select all that apply) |
| 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 | [ ]  Non‑conjugative plasmids[ ]  lambda bacteriophage[ ]  lambdoid bacteriophage[ ]  Fd, F1 or M13 bacteriophage[ ]  None (non‑vector systems) |
| 2 | Bacteria | [ ]  *Bacillus* – asporogenic strains of the following species with a reversion frequency <10–7:(a) *B. amyloliquefaciens*(b) *B. licheniformis*(c) *B. pumilus*(d) *B. subtilis*(e) *B. thuringiensis* | [ ]  Non‑conjugative plasmids[ ]  Other plasmids and phages whose host range does not include *B. cereus*, *B. anthracis* or any other pathogenic strain of *Bacillus*[ ]  None (non‑vector systems) |
| 3 | Bacteria | [ ]  *Pseudomonas putida* strain KT2440 | [ ]  Non‑conjugative plasmids [ ]  None (non‑vector systems) |
| 4 | Bacteria | [ ]  The following *Streptomyces* 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* | [ ]  Non‑conjugative plasmids[ ]  Plasmids SCP2, SLP1, SLP2, PIJ101 and derivatives[ ]  Actinophage phi C31 and derivatives[ ]  None (non‑vector systems) |
| 5 | Bacteria | [ ]  *Agrobacterium radiobacter*[ ]  *Agrobacterium rhizogenes* (disarmed strains only)[ ]  *Agrobacterium tumefaciens* (disarmed strains only) | [ ]  Disarmed Ri or Ti plasmids[ ]  None (non‑vector systems) |
| 6 | Bacteria | Any of the following: [ ]  *Allorhizobium* species[ ]  *Corynebacterium glutamicum*[ ]  *Lactobacillus* species[ ]  *Lactococcus lactis*[ ]  *Oenococcus oeni* syn. *Leuconostoc oeni*[ ]  *Pediococcus* species[ ]  *Photobacterium angustum*[ ]  *Pseudoalteromonas tunicata*[ ]  *Rhizobium* species[ ]  *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis*[ ]  *Streptococcus thermophilus*[ ]  *Synechococcus* species strains PCC7002, PCC7942 and WH8102[ ]  *Synechocystis* species strain PCC 6803[ ]  *Vibrio cholerae* CVD103‑HgR[ ]  *Zymomonas mobilis* | [ ]  Non‑conjugative plasmids[ ]  None (non‑vector systems) |
| 7 | Fungi | Any of the following:[ ]  *Kluyveromyces lactis*[ ]  *Neurospora crassa* – laboratory strains[ ]  *Pichia pastoris*[ ]  *Saccharomyces cerevisiae*[ ]  *Schizosaccharomyces pombe*[ ]  *Trichoderma reesei*[ ]  *Yarrowia lipolytica* | [ ]  All vectors[ ]  None (non‑vector systems) |
| 8 | Slime moulds | [ ]  *Dictyostelium* species | [ ]  *Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2[ ]  None (non‑vector systems) |
| 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 *in vitro* | [ ]  Plasmids[ ]  Replication defective viral vectors unable to transduce human cells[ ]  polyhedron minus forms of the baculovirus *Autographa californica* nuclear polyhedrosis virus (ACNPV)[ ]  None (non‑vector systems) |
| 10 | Tissue culture | [ ]  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 | [ ]  Disarmed Ri or Ti plasmids in *Agrobacterium radiobacter*, *Agrobacterium rhizogenes* (disarmed strains only) or *Agrobacterium tumefaciens* (disarmed strains only)[ ]  Non‑pathogenic viral vectors[ ]  None (non‑vector systems) |

| 6 Class of modified trait and Gene(s) Responsible (insert details where applicable) |
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| 1. Abiotic stress resistance
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| 1. Altered agronomic characteristics
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| 1. Altered biocontrol characteristics
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| 1. Altered bioremediation characteristics
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| 1. Altered biosensor characteristics
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| 1. Altered horticultural characteristics
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| 1. Altered nutritional characteristics
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| 1. Altered pharmaceutical characteristics
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| 1. Altered physical product characteristics
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| 1. Altered physiological characteristics
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| 1. Antibiotic resistance
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| 1. Antigen expression
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| 1. Attenuation
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| 1. Bacterial resistance
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| 1. Disease resistance
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| 1. Fungal resistance
 |  |
| 1. Growth factor expression
 |  |
| 1. Herbicide tolerance
 |  |
| 1. Immuno -modulatory protein expression
 |  |
| 1. Oncogene
 |  |
| 1. Pest resistance
 |  |
| 1. Pesticide resistance
 |  |
| 1. Protein expression
 |  |
| 1. Reporter/marker gene expression
 |  |
| 1. Virus resistance
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| 1. Other, describe
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| 7 | Persons undertaking the dealing |
| *The IBC must assess whether the persons or categories of persons have appropriate training and experience to undertake the dealing. This* includes persons beyond the persons conducting the research, such as persons involved in importation, transportation and disposal of GMOs*.* **Note: Appropriate training for personnel undertaking research includes** successful completion of Biosafety Training, reading the Biosafety Manual and completing a Physical Containment (PC) facility induction for all PC facilities where you will be undertaking work.  |
| **List all persons known to be involved at the time of writing this application -** *d*etails of additional persons can be added later by notifying the IBC via email. |
| **Name** | **Category** **Research Staff/ Student/ Other** | **Biosafety Training completed?** |
| **Yes/ No** | **If yes, when (year) & where (organisation)?** | **If no, what measures are in place to ensure all personnel are adequately trained before commencing the dealing?** |
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| 8 | Facilities to be Used |
| *All facilities to be used must be authorised. Please list all facilities intended to be used at the time of writing this application – details of additional facilities can be added later by notifying the IBC via email.* Note: If you have any questions regarding any facilities or “local contact persons”, please contact the Biosafety Officer: ibcadmin@flinders.edu.au |
|  | **Facility 1** | **Facility 2** | **Facility 3** |
| **Organisation/Site** |       |       |       |
| **Room Number(s)** |       |       |       |
| **Building** |       |       |       |
| **Local contact person** |       |       |       |
|  | **Facility 4** | **Facility 5** | **Facility 6** |
| **Organisation/Site** |       |       |       |
| **Room Number(s)** |       |       |       |
| **Building** |       |       |       |
| **Local contact person** |       |       |       |

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| 9 | Storage Locations |
| *All storage locations used must be authorised. Storage of GMOs outside of a certified PC facility is permitted, but must be authorised by the IBC. Unauthorised storage of GMOs is an offence under the Act.* |
|  | **Location 1** | **Location 2** | **Location 3** |
| **Organisation/Site** |       |       |       |
| **Room Number(s)** |       |       |       |
| **Building** |       |       |       |
| **Storage location** **(e.g. locked -80 freezer in corridor; fridge # 1, etc.)** |       |       |       |

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| 10 | Project Supervisor Declaration |
| Please ensure you understand each statement and your responsibilities and then sign the application form (electronic signatures accepted). |
| I have read, considered and understand my responsibilities under the Gene Technology Act 2000 and agree to undertake the dealing outlined in this application in accordance with the relevant Office of the Gene Technology Regulator guidelines and regulations (including, but not limited to all disposal, transport and storage) <http://www.ogtr.gov.au>  |
| I am aware of my responsibilities in relation to ensuring that any personnel conducting this work are appropriately trained and are aware of and follow the relevant guidelines and regulations. |
| I have considered the potential risks that the conduct of this dealing could pose to people and/or the environment and will implement appropriate actions and precautions to minimise these risks.  |
| Where a GMO is received from sources outside the institution responsible for the project, I will take steps to confirm its identity. |
| In the event of an unintentional release of a GMO I am aware that I must put into place the appropriate responses to contain the release and I will inform the IBC as soon as practicable of any incidents, accidents or unintentional releases involving GMOs. |
| I am aware that breaches of the legislation are serious matters and that penalties could include loss of OGTR Accreditation status for the organisation, imprisonment and/or substantial fines. |
| Name |  | Signature |  | Date |

**Please submit this application form to the IBC via email:** **ibcadmin@flinders.edu.au**

***Please retain a copy of your completed application for your own records.***

# APPENDIX 1: – Approvals/Notifications/Compliance Checklist

| Note that if your dealing involves any of the following, you must also carry out the action required. **Where approval is required, it is your responsibility to obtain that approval.**  |
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| **Does the dealing involve:** | **Action required:** |
| **Animals, animal tissues or animal cells?**  | **You must obtain approval from an Animal Welfare Committee.** At Flinders: <https://staff.flinders.edu.au/research/integrity/animal-ethics>Animal Ethics Officer telephone: 8201 5962Email: animal.welfare@flinders.edu.au |
| **Human subjects, tissues, body products or personal information?**  | **You must obtain approval from a Human Research Ethics Committee.** At Flinders:[Southern Adelaide Clinical Human Research Ethics Committee](http://www.sahealth.sa.gov.au/wps/wcm/connect/public%2Bcontent/sa%2Bhealth%2Binternet/about%2Bus/health%2Band%2Bmedical%2Bresearch/salhn%2Bresearch/undertaking%2Bresearch/southern%2Badelaide%2Bclinical%2Bhuman%2Bresearch%2Bethics%2Bcommittee)Email: Health:SALHNofficeforresearch@sa.gov.au |
| **Radioactive substances or ionizing radiation?**  | **At Flinders you must notify the Radiation Safety Officer:** <https://staff.flinders.edu.au/workplace-support/whs/contact-whs> |
| **Carcinogenic substances (scheduled)?** | **You must follow the *Managing Risks of Hazardous Chemicals in the Workplace Code of Practice*.** At Flinders, contact the Work Health & Safety Unit for advice. Telephone: 8201 3024 |
| **Hazardous substances?**  | **At Flinders, you must comply with the Hazardous Chemicals Safety Management Procedures:** <http://www.flinders.edu.au/ppmanual/health-safety/workplace-substances-management.cfm>  |
| **Import of biological materials from overseas?** | **A Department of Agriculture import permit may be required.** Search the BICON database for import conditions for your goods: <https://bicon.agriculture.gov.au/BiconWeb4.0/>For shared-use permits held by the University for commonly imported items, please view the list of available permits and apply via [ServiceOne](https://serviceone.flinders.edu.au/) > Research Services > Importing, exporting or transporting biological goods > I am applying to use a University-held permit.For items not covered by shared-use permits, a permit must be arranged through the Department of Agriculture by the researcher where required. Assistance can be provided by RDS – biosecurity@flinders.edu.au  |

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