**Application for Ministerial Concurrence**

**to Perform LD50 Tests**

**Explanatory Notes**

1. A Lethal Dose 50 (LD50) test is:

“The animal research procedure in which any material or substance is administered to animals for the purpose of determining the concentration or dose of the material or substance which will achieve any predetermined death rate”.

1. Persons who seek approval to perform LD50 tests on animals must, in addition to making application to an Animal Ethics Committee (AEC), apply for the Minister for Agriculture’ concurrence to conduct the tests.
2. The Animal Research Review Panel (ARRP) will assess the application (for concurrence to perform LD50 tests) and make recommendations to the Minister as to whether the application should be approved. It is the responsibility of the institution making the application to provide the Minister with sufficient, detailed information so that the application can be properly assessed.
3. In particular any relevant legislation which requires toxicity testing in animals, for example for registration of a product, should be disclosed in the application.
4. The project should be given preliminary assessment by an AEC before an application is made for Ministerial concurrence to perform an LD50 test.
5. A separate application must be submitted by an applicant for **each** project which involves LD50 tests on animals.
6. Documents required to be submitted for each application:

1. A completed application form for the Minister’s concurrence to perform LD50 tests;

2. A completed AEC application which has been submitted to an AEC for preliminary assessment; and

3. If the proposal is part of an ongoing testing program, a report which summarises the results of LD50 tests which have been performed by the authority holder during the preceding 12 months. The report must supply information about the actual numbers of animals that were used for these tests, how many died during the testing procedure, how many became clinically ill, and how many were humanely killed. Any improvements or progress which has been made in the course of the year should be described, particularly towards the goals of replacement, refinement and reduction in the use of animals.

1. Applications should be submitted well in advance of the proposed starting date as assessment of each application takes 2 to 3 months.
2. Completed applications which have been given a preliminary assessment by an AEC should be submitted to:

Biosecurity & Food Safety Division

Department of Primary Industries and Regional Development

bfs.admin@dpi.nsw.gov.au

# Application for Ministerial Concurrence to Perform LD50 Tests

An application for permission to perform LD50 tests and a completed Animal Ethics Committee application should be supplied for **each** project which involves LD50 testing. Please attach extra pages if space provided is insufficient.

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| **1. Proposed Study or Project** |
| 1.1 Title of Proposed Study: |
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| 1.2 Description of Study: |
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| 1.3 Lay Description of Study: |
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| 1.4 Purpose of Study: |
|  |
| 1.5 Location of Study: |
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| **2. Regulatory Requirements** |
| 2.1 Are these tests required by State or Commonwealth legislation? *If so, give details of the relevant legislative provisions.* |
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| 2.2 Are these tests required for export of the compound being tested? *If so, name the countries which require these tests.* |
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| **3. Alternatives to Animal Use** |
| 3.1 What alternatives are available to avoid the use of death as an endpoint? *For example, use of clinical, biochemical or pathological changes as an indicator of the potency of the compound.* |
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| 3.2 What alternatives are available to replace the use of animals in these studies? *For example, in vitro assays such as ELISAs.* |
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| 3.3 What alternatives are available to reduce the number of animals used in these studies? |
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| 3.4 What is the justification for the number of animals used in these studies? |
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| **4. Information about animals to be used** |
| 4.1 Species: |
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| 4.2 Strain: |
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| 4.3 Range of body weights: |
|  |
| 4.4 Sex or sex ratio: |
|  |
| 4.5 Age range: |
|  |
| 4.6 Number: |
|  |
| 4.7 Genetic requirements: |
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| 4.8 Health requirements: |
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| 4.9 Other special requirements: |
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| 4.10 Origin of animals (*Supplier*): |
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| **5. Information about experimental procedures** |
| 5.1 Name of agent or compound to be tested: |
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| 5.2 Description of agent/compound to be tested: (*Include details on any features of the compound (such as physical and chemical composition) which might influence animal health)* |
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| 5.3 Route of administration: |
|  |
| 5.4 Dose or concentration: |
|  |
| 5.5 Will the compound be administered more than once? *If so, provide details.* |
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| 5.6 What are the anticipated immediate and delayed effects of the compound on the health and well-being of the experimental animals? |
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| 5.7 Will analgesia or anaesthesia be used? *If so, provide details of the drugs to be used, their dose rates, administration routes and experience of personnel in their use and the stage of the experiment at which they will be used.* |
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| 5.8 Describe the level of care and supervision which will be given to animals which develop clinical illness during the study. |
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| 5.9 How many animals are expected to die with acute toxicity in the course of the experiment? |
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| 5.10 What provisions have been made to treat or kill animals adversely affected by the procedures? |
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| 5.11 What is the fate of the surviving animals after the experiment? |
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| 5.12 If animals are to be killed state the technique to be used and the employment positions of the personnel who will be responsible (e.g. veterinarian, animal attendant). |
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| **6. Personnel** |
| 6.1 List the staff positions involved in the care of animals in this study. |
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| **7. Hazards** |
| 7.1 Does this procedure involve any hazards to staff or animals, such as infectious agents, ionizing radiation or toxic chemicals? *If so, describe the measures used to limit the hazards to staff, animals and equipment.* |
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| 1. **Ongoing testing programme**   *(To be completed if the project is part of an ongoing testing programme)* |
| 8.1 Please attach a report which summarises the results of LD50 testing conducted in the last 12 months. |
| 8.2 During LD50 testing in the last 12 months:  8.2.1 Number of animals used: |
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| 8.2.2 Number of animals that died during the testing procedure (not including those that were euthanased): |
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| 8.2.3 Number of animals that became clinically ill: |
|  |
| 8.2.4 Number of animals that were euthanased (as an early end point): |
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| 8.2.5 Any improvements or progress made in the course of the last 12 months, especially towards the goals of replacement, refinement and reduction in the use of animals: |
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| **9. Completed AEC Application Form** |
| 9.1 Please attach a completed AEC application form and include the results of its assessment by the supervising AEC. |

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| **10. Administrative Information** | |
| Establishment: |  |
| Address: |  |
| Animal Ethics Committee Chairperson: |  |
| Phone: |  |
|  | |
| Chief Investigator: |  |
| Qualifications: |  |
| Department: |  |
| Phone: |  |
|  | |
| Associate Investigator (1): |  |
| Qualifications: |  |
| Department: |  |
| Phone: |  |
|  | |
| Associate Investigator (2): |  |
| Qualifications: |  |
| Department: |  |
| Phone: |  |

**11. Declaration**

I declare the information supplied to be true, complete and correct.

Investigator:

|  |  |
| --- | --- |
| Name |  |
| Department |  |
| Signature |  |
| Date |  |

Associate Investigators: (1)

|  |  |
| --- | --- |
| Name |  |
| Department |  |
| Signature |  |
| Date |  |

Associate Investigators: (2)

|  |  |
| --- | --- |
| Name |  |
| Department |  |
| Signature |  |
| Date |  |

Animal Ethics Committee Chairperson:

|  |  |
| --- | --- |
| Name |  |
| Department |  |
| Signature |  |
| Date |  |

Head of Institution:

|  |  |
| --- | --- |
| Name |  |
| Department |  |
| Signature |  |
| Date |  |

**11. Privacy Notice**

The information provided by the applicant is being collected for the purpose of enabling assessment of the application for Ministerial concurrence under the *Animal Research Act 1985*. It will be used by NSW Department of Primary Industries and Regional Development for administration of the Act and will be provided to the Animal Research Review Panel and the Minister for Agriculture. The information has been provided because it is required by law and will be stored securely within the NSW Department of Primary Industries and Regional Development. You may access or correct your personal information by contacting the Compliance & Integrity Systems in writing via [bfsadmin@dpird.nsw.gov.au](mailto:bfsadmin@dpird.nsw.gov.au) or NSW Department of Primary Industries and Regional Development, Locked Bag 21, Orange NSW 2800.

**Consent for names and addresses to be included on a mailing list**

The *Privacy and Personal Information Protection Act 1998* obliges NSW Department of Primary Industries and Regional Development to make you aware of the purposes for which we might use the contact details with which you supply us. In order to comply with the requirements of the Act we are obliged to ask you to indicate whether or not you wish to have your name and address included on a mailing list for the purpose of distributing information regarding the *Animal Research Act 1985*. The mailing list will remain in use until Ministerial concurrence for your LD 50 test lapses and you may amend, or remove, your contact details from the mailing list at any time by contacting the, Compliance & Integrity Systems, NSW Department of Primary Industries and Regional Development, bfsadmin@dpird.nsw.gov.au

Please indicate your preference with an X:

**Chief Investigator**

Include my personal details on the Animal Welfare Branch mailing list.

Do not include my personal details on the Animal Welfare Branch mailing list.

|  |  |
| --- | --- |
| Name |  |
| Department |  |
| Signature |  |
| Date |  |

**AEC Chair**

Include my personal details on the Animal Welfare Branch mailing list.

Do not include my personal details on the Animal Welfare Branch mailing list.

|  |  |
| --- | --- |
| Name |  |
| Department |  |
| Signature |  |
| Date |  |

**Chief Executive Officer**

Include my personal details on the Animal Welfare Branch mailing list.

Do not include my personal details on the Animal Welfare Branch mailing list.

|  |  |
| --- | --- |
| Name |  |
| Department |  |
| Signature |  |
| Date |  |

Please return the completed form to:

**Biosecurity & Food Safety Division**

NSW Department of Primary Industries and Regional Development

[bfs.admin@dpi.nsw.gov.au](mailto:bfs.admin@dpi.nsw.gov.au)

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