# Department of Primary Industries and Regional Development



November 2024

# Guidance on completing Form L: Animal Use Statistics

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# **Explanatory notes**

### What is Form L?

<u>Form L</u> is the format in which the NSW Department of Primary Industries and Regional Development (the department) collects information on Animal Ethics Committee (AEC) activity and animal use in research and teaching which occurred in NSW during a calendar year (i.e. 1 January to 31 December). Under the *Animal Research Act 1985* (the Act) this information must be submitted by all accredited research establishments and holders of animal research authorities by 31 March of the following year.

Form L consists of five sections to be completed and submitted online:

- AEC activity report
- Lethality testing report (if lethality testing was conducted)
- Independent researcher report (if independent researchers were supervised)
- General animal use statistics
- Cat and dog reporting

## How do I submit the Form L?

Form L is submitted by completion of the online Form. This includes completing and uploading:

NSW animal use statistics spreadsheet, using the provided template (spreadsheet template)

The most recent AEC annual report

### When do I need to submit the Form L return?

All Form L returns must be submitted to the department no later than 31 March of the year following the reporting period.

Please note: The submission of a completed Form L is required under Clause 24 of the Animal Research Regulation 2021. The maximum penalty for non-compliance with this requirement is \$1,100.

### Where do I get help to complete the form?

If you have read the explanation for each section of the form and still have questions you should email <a href="mailto:bfs.admin@dpi.nsw.gov.au">bfs.admin@dpi.nsw.gov.au</a> with the subject line: FORM L submission query.

# What happens to the information collected?

The information is collated and published on the <u>Animal Ethics Infolink website</u> (without identification of individual establishments).

# My research is supervised by the Secretary's AEC. Do I need to submit the Form L?

No. Accredited research establishments and individuals using the Secretary's AEC are not required to submit Form L, as this information is compiled by the department.

# AEC activity report

This section requests information regarding AEC activities and provides an opportunity to report on the implementation of the principles of Replacement, Reduction and Refinement.

It includes the mandatory uploading of the most recent AEC annual report. Guidance on AEC annual reporting and a suggested template are provided on the Animal Ethics Infolink website.

# Lethality testing report

An accredited research establishment must keep records of all lethality tests that are approved by its AEC during the period 1 January to 31 December and give a copy of these records to the Animal Research Review Panel following the 12 month reporting period. Each record must be kept for a period of 7 years after the record is made. A separate lethality testing report form should be completed for each lethality test approved.

The Act defines a lethality test as "an animal research procedure in which any material or substance is administered to animals for the purpose of determining whether any animals will die or how many animals will die".

Lethality testing includes, but is not limited to, LD50 testing (as defined in the Act). It includes any procedure where substances are given to animals to test whether any animals will die or to measure how many animals will die.

# Independent researcher report

An accredited research establishment must keep records of all applications for animal research authorities that are made to it by independent researchers during the period 1 January to 31 December and give a copy of these records to the Secretary following the 12 month reporting period. Each record must be kept for a period of 7 years after the record is made. A separate independent researcher report form should be used for each animal research authority application.

The Act defines an accredited research establishment independent researcher as "a person who carries out animal research, or applies for an authority to carry out animal research, otherwise than on behalf of the accredited research establishment".

### General animal use statistics

- Please use the <u>spreadsheet template</u>.
- See Appendix 1 for an example of a completed spreadsheet.
- Please see the guidance on ensuring data accuracy.

### **Collecting Statistics**

Animal use data are categorised by purpose, procedure, species and fate. Animals should be counted in each project where they are used and should be included for each calendar year they are in a long-term project.

Supervising AECs may wish to gather the data from each establishment or independent researcher they supervise and include these with their own dataset. However, the responsibility for submitting data rests with the accredited research establishment carrying out the research. 'Independent researchers' should be included in the AEC's data.

Some AECs may prefer that researchers complete the spreadsheet whilst other AECs may wish to collect the information from researchers and complete the spreadsheet themselves.

Whatever method is used, it should be accurate and be used consistently (i.e. use the same method each year).

Please confirm with the establishments supervised as to how they wish to submit their data, to avoid duplication.

# Categorisation of procedures

Much of the animal research and teaching carried out will be relatively easy to categorise. The procedure categories are intended to give some indication of the **impact** of procedures on the animals used. Use the <u>Animal Ethics Infolink: Guide to reporting categories</u> and <u>Appendix 2 codes summary</u> to help categorise each procedure. The examples provided in the guide are only a guide and do not exclude otherwise unlisted procedures which are judged to have a similar level of impact.

# Multiple species and/or procedures in a single project

Some projects will use more than one **species**. Some projects will have animals that are subject to different categories of **procedures**. This may occur, for example, where control and test groups of animals are subjected to different procedures. Another example is wildlife surveys where a variety of species are involved. In these cases, the projects should be split into multiple rows in your

spreadsheet so that each row will only have one species and one category of procedure. Each row should have the same project number (as given by the AEC in approving the project). See examples in <u>Appendix 1</u>.

#### Fate of animals

This column **MUST** be completed where species S31 domestic cats or S32 domestic dogs have been used. This column may also be completed where other species are used and it is recommended that this information be provided.

For each project, include additional rows in your spreadsheet where there are different fates of animals within the same project and/or multiple species and multiple procedure categories within the same project. Each row should have the same project number (as given by the AEC in approving the project). See examples in Appendix 1.

## Stages of development

Some projects, for example breeding or genetically modified animal production, may use animals that are at a very early stage of development or use embryonated eggs. It is reasonable to count only those immature forms that have reached a certain stage of development.

In general, include embryonic, foetal and larval forms once the development of that form has progressed beyond **half the gestation or incubation period** for the species, or it becomes capable of independent feeding (whichever is sooner). Some differences are listed for amphibians and fish in the following summary:

**Mammals** From half-gestation onwards

Birds From half-incubation onwards

**Reptiles** From half-incubation or half-gestation onwards

**Amphibians** Fully metamorphosed juveniles and older

**Fish** Fully metamorphosed juveniles and older

Where the procedure is carried out on an immature form that goes on to develop to the above stage or beyond, (e.g. manipulation of day-old embryos that then develop and are born), these should be included.

Please note that although the use of the immature forms prior to the above thresholds does not need to be reported, their use still requires AEC approval.

#### Re-use of animals

Each year, an animal should be counted once for **each project** in which it is used. For example, where animals are used repeatedly in one project (e.g. teaching animal handling once a week) these animals are counted once for their inclusion in this project. If the project is renewed the following year, then they are counted once again in that subsequent year. If these same animals are used in two projects in one year (e.g. weekly handling and a short behavioural study), they will be counted twice (once for each project).

It is important that they are counted in this way as this more closely reflects the overall use of animals for research and teaching. It may be noted that an animal has been re-used in the comments column, but this is not mandatory.

### Production of genetically modified animals

The **production** of genetically modified animals can involve a wide range of procedures, making it difficult to assign them to a particular procedure category. As such, a dedicated procedure category has been included for these animals to permit easier collection of data. It effectively includes ALL animals used in genetically modified animal production other than the final progeny which are used in a different procedure category.

### Wildlife surveys and observation studies

For wildlife surveys and observation studies, if individual animals are unable to be identified or individually counted, (for example: acoustic recording of frog calls, visual estimates of flying bats or remote camera images to detect species presence or absence) then these do not need to be reported. Estimates of numbers should not be reported. Such reporting leads to inaccuracy and over-reporting.

#### Field studies

When reporting on field studies using animals primarily held for commercial purposes, only report the animals involved in the study, not the whole herd/flock, as this results in over-reporting.

## Submitting the General Animal Use Statistics

- Data must be submitted as a spreadsheet and in the spreadsheet template format.
- Data submitted as word or pdf documents will not be accepted.
- The spreadsheet template is provided to reduce inaccuracies such as entering species codes
  that do not exist, or entering purpose and procedure codes in the wrong columns. The
  spreadsheet template provides drop-down lists for selecting codes, which helps validate the
  data as it is entered.
- The use of drop-down lists in the spreadsheet template is strongly encouraged to reduce errors. If data are instead entered manually, copied and pasted from another source or transferred from a database to the spreadsheet, the establishment is responsible for ensuring the resulting submission conforms to the spreadsheet template format and rules.
- The provided alphanumeric codes for purpose (A), procedure (P), species (S) and fate of animal (F) must be used. The spreadsheet template includes a 'Code Mapping' sheet for your reference.

Note: See <u>Appendix 2</u> for a codes summary and the <u>Animal Ethics Infolink: Guide to reporting categories</u> for code definitions and examples.

Description of Columns:

#### A: Year

Enter the calendar year, in YYYY format ensuring that all rows relate to animal use in the relevant reporting year.

#### **B:** Project number

Enter the project number as given by the AEC.

#### C: Purpose

- Purpose codes have an A in front of the number.
- Enter the most appropriate alphanumeric code (A1-A10) to describe the primary purpose of the project (one purpose only for each project should be entered).

#### D: Procedure

- Procedure codes have a P in front of the number.
- Enter the highest appropriate alphanumerical code (P1-P9) to describe the type of procedures carried out on the animals in the project.
- Where 'Death as an endpoint' or 'Production of genetically modified animals 'applies, animals must be placed in these categories (P8 or P9) rather than any others that might also appear appropriate.
- Multiple rows should be recorded for a single project where different animals within the project are subjected to different procedure categories.

#### **E:** Species

- Species codes have an S in front of the number.
- Enter the alphanumeric code to describe the species or species group used in the project.
- Species codes are not sequential.
- There are no species codes S15, S19, S22, S25, S26, S44 or S55, and the highest number is S56.
- Multiple rows should be recorded for a single project where more than one species is used in a project.
- See guidance on improving accuracy of species reporting.

#### F: Fate of animal

- Fate codes have an F in front of the number.
- This column MUST be completed where species domestic cats (S31) or domestic dogs (S32) have been used.
- This column may also be completed where other species are used and it is recommended that this information be provided.

• Multiple rows should be recorded for a single project where there are different fates of animals within a project.

#### G: Number used

Enter the number of animals *that were actually used* (i.e. not just the number supplied or authorised) in the project in the year for which statistics are being collected. See <u>guidance on improving</u> accuracy of numbers reporting.

#### H: Comments

- Use this column to communicate any other information, e.g. if you are unsure whether the project used animals old enough to be counted (see *Stages of development*).
- You may wish to explain why an unusual procedure and species combination is being reported (see Certain combinations should trigger checking)
- You may also wish to note re-use of animals here, although this information is not mandatory (see *Re-use of animals*).

# Reporting of dogs and cats

These sections must be completed by any accredited research establishment that kept domestic dogs or cats for research during the period 1 January to 31 December of the reporting year. There is a separate section for each species.

This includes any domestic dog or cat kept for research during the reporting year, regardless of whether they were used in a project. This information must be provided in addition to the General Animal Use Statistics.

This does not include any privately owned domestic dogs or cats that were primarily kept by an individual for reasons other than research (e.g., as a companion animal).

Information required for the reporting year includes:

- Numbers of dogs and cats kept, obtained, bred, and supplied (Note: this is number of animals kept rather than number of times animals were used)
- Fate of dogs and cats (including rehoming and euthanasia)
- Numbers and outcomes of any applications made to the Animal Research Review Panel under section 54C(4)(a) of the Act.

# Ensuring data accuracy

#### Year

All data in your spreadsheet must relate to projects undertaken in the correct reporting year. Column A should not contain any other years.

## Species codes

Avoid entering incorrect species codes such as S558 instead of S55B.

- Do not add 0 in front of species numbers S1-S9.
- There are NO species codes S15, S19, S22, S25, S26, S44 or S55. Please make sure these codes are not used.
- Using the spreadsheet template will help reduce these sources of error by using the dropdown lists.

### Purpose and procedure

The order of purpose and procedure columns must be consistent with the order on the spreadsheet template (i.e. C: Purpose then D: Procedure)

### Procedure P8: Death as an endpoint

Entries with procedure category P8 Death as an endpoint should always be checked to ensure this is the correct procedure category, noting the definition. Note that P8 does not apply where animals are euthanased as part of a project.

#### Fate of animals

If species S31 domestic cats or S32 domestic dogs are entered then column F: Fate of animal MUST be completed.

#### Numbers used

- Ensure the year is not entered by mistake in place of the number of animals used. Filter or sort your data to check this has not occurred.
- Large numbers should be double checked to make sure they are correct.
- To help detect over-reporting of animals used, all numbers used for each project should be checked against the number approved for that project.
- If the species code S24 (Amphibians) has been used, check whether this was tadpoles. Tadpoles do not need to be reported unless they go on to fully metamorphosed development. See <u>Stages</u> <u>of development</u> for guidance on what immature forms do and do not need to be reported.
- Observation studies should only be reported where those animals were individually **counted** (not just estimated).

# Researchers/establishments are responsible for data integrity

Researchers must check the information submitted to ensure it matches what actually occurred and the numbers used. Where incorrect data is reported (such as inaccurate numbers or incorrect assigning of purpose and procedure), these data may be reflected in the department's annual statistics report.

# Certain combinations should trigger checking

Unusual or unexpected combinations of purpose and procedure categories reported together should be checked for accuracy. These include:

Purpose	Procedure
A1 Stock breeding	P5 Major surgery with recovery (except laboratory mammals) P7 Major physiological challenge P8 Death as an endpoint
A2 Stock maintenance	P5 Major surgery with recovery P7 Major physiological challenge P8 Death as an endpoint
A3 Education	P5 Major surgery with recovery P7 Major physiological challenge P8 Death as an endpoint P9 Production of genetically modified animals
A4 Human and animal biology	P8 Death as an endpoint
A5 Human or animal health and welfare	P8 Death as an endpoint
A6 Animal management and production	P8 Death as an endpoint
A7 Environmental study	P5 Major surgery with recovery P7 Major physiological challenge P8 Death as an endpoint P9 Production of genetically modified animals
A8 Production of biological products	P5 Major surgery with recovery P7 Major physiological challenge P8 Death as an endpoint P9 Production of genetically modified animals
A9 Diagnostic procedures	P5 Major surgery with recovery P7 Major physiological challenge P8 Death as an endpoint P9 Production of genetically modified animals
A10 Regulatory product testing	P9 Production of genetically modified animals

Figure 1: Table depicting combinations of purpose and procedure codes that should trigger checking.

# AEC assessment and approval

Animal use data to be submitted via Form L should be presented to the responsible AEC for assessment and approval prior to submission.

<sup>©</sup> State of New South Wales through DPIRD 2024. The information contained in this publication is based on knowledge and understanding at the time of writing (November 2024). However, because of advances in knowledge, users are reminded of the need to ensure that the information upon which they rely is up to date and to check the currency of the information with the appropriate officer of the DPIRD or the user's independent adviser.

# Appendix 1: An example of a completed spreadsheet

1	А	В	С	D	Е	F	G	Н
2	Year	Project number	Purpose	Procedure	Species	Fate	Number used	Comments
3	2023	09/215	A1	P1	S1		30	
4	2023	09/217	A8	P8	S1		24	
5	2023	08/001	A5	P4	S2		12	
6	2023	07/002	A4	P3	S1		6	
7	2023	07/002	A4	P6	S1		10	
8	2023	07/003	A1	P1	S3		4	
9	2023	07/003	A1	P1	S4		8	
10	2023	08/183	A5	P2	S1		23	
11	2023	08/183	A5	P2	S3		20	
12	2023	08/183	A5	P4	S1		15	
13	2023	08/183	A5	P4	S3		12	
14	2023	09/004	A7	P1	S28		30	
15	2023	09/001	A1	P1	S1		20	
16	2023	07/002	A5	P2	S2		34	Smith & Co.
17	2023	908218	A7	P3	S55B		12	Joe Bloggs
18	2023	18/020	A5	P1	S32	F4	20	
19	2023	18/035	A4	P1	S31	F2	10	
20	2023	18/035	A4	P1	S31	F5	2	
21	2023	18/035	A4	P2	S31	F6	5	

Figure 2: Example of a spreadsheet submitted by an establishment (that has its own AEC) for the calendar year.

- Rows 6-7: Example of one project with differing procedure categories and the same species of animals.
- Rows 8-9: Example of one project with the same procedure categories and differing species of animals.
- Rows 10-13: Example of one project with differing procedure categories and differing species of animals.
- Rows 16-17: Example of where accredited research establishment Smith & Co. and independent researcher Joe Bloggs have been included in the Form L submission as they are supervised by this establishment's AEC and the establishment chose to include them with its From L statistics.
- Row 18: Example of one project using domestic dogs where all animals were privately owned and remained with the owners.
- Rows 19-21: Example of one project using domestic cats with differing procedure categories and differing fates of animals.

# Appendix 2: Summary of codes

PURPOSE					
A1	Stock breeding				
A2	Stock maintenance				
АЗ	Education				
Α4	Research: Human or animal biology				
A5	Research: Human or animal health &				
CA	welfare				
A6	Research: Animal management or				
AU	production				
Α7	Research: Environmental study				
8A	Production of biological products				
Α9	Diagnostic procedures				
A10	Regulatory product testing				

	PROCEDURE					
P1	Observation involving minor interference					
P2	Animal unconscious without recovery					
Р3	Minor conscious intervention					
P4	Minor surgery with recovery					
P5	Major surgery with recovery					
P6	Minor physiological challenge					
P7	Major physiological challenge					
P8	Death as an end point					
P9	Production of genetically modified					
	animals					

	FATE					
F1	Retained in project					
F2	Retained for use in other projects or supplied to another establishment / individual for research					
F3	Retired from research and kept by the establishment/ individual					
F4	Privately (non-research) owned and remained with owner					
F5	Rehomed (as companion animal to private (non-research) home or rehoming organisation)					
F6	Euthanased or died related to the project					
F7	Euthanased or died unrelated to the project					
F8	Euthanased because unsuitable to be rehomed					
F9	Euthanased because unable to find a suitable home					
F10	Remain free living in the wild or released to the wild					

SPECIES					
Laboratory S1		Mice S5		Hamsters	
		Rats	S6	Ferrets	
	S3	Guinea Pigs		Other laboratory	
	C4	Rabbits	S7	mammals (not	
S4		Rappits		primates)	
Domestic	S8	Sheep	S11	Horses	
mammals	S9	Cattle	S12	Goats	
	S10	Pigs	S14	Deer	
	S8	Sheep S31		Cats	
	S9	Cattle S32 Dogs		Dogs	
	S10	Pigs S33		Other domestic mammals	
Birds	S13	Poultry	S18	Native Captive	
	S16	Exotic Captive	S20	Native Wild	
	S17	Exotic Wild	S21	Other birds	
Aquatic	S23	Fish			
animals		Cephalopods		Crustaceans	
	S23A	(reporting not	S23B	(reporting	
		mandatory)		not mandatory)	
Amphibians	S24	Amphibians			
Reptiles	S27	Lizards	S29	Turtles and Tortoises	
	S28	Snakes	S30	Other reptiles	
Primates	S34	Marmosets	S36	Baboons	
	S35	Macaques S37		Other primates	
Native	S38	Macropods	S44A	Monotremes	
mammals	S39	Possums and gliders	S44B	Bandicoots	
	S40	Native rats and mice	S44C	Bats	
	S41	Dasyurids	S44D Other native man		
	S42	Wombats	S44E	Seals	
	S43	Koalas	S44F	Whales and dolphins	
Exotic feral	S45	Camels	S52	Pigs	
mammals	S46	Cats	S53	Rabbits	
	S47	Cattle	S54	Rats	
	S48	Goats S55		Dingo/Wild Dogs	
	S49	Hares	S55B	Foxes	
	S50	Horses		Other exotic feral	
	S51	Mice	S55C	mammals	
Exotic zoo animals	S56	Exotic zoo animals			

See <u>Animal Ethics Infolink: Guide to</u> reporting categories for category definitions and examples.