

Category 25 application

- [1] Assessment of a trial protocol**
- [2] Pre-registration or pre-approval assessment of data**
- [3] Application requiring technical assessment and not covered by any other Category**

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1. DEFINITION

Schedule 6 of the Agvet Code Regulations describes a Category 25 application as:

Any other application:

- (a) that is not made under section 10 of the Code; and*
- (b) that is not of a kind listed in an item of this Schedule;*
requiring assessment of a technical nature.

Category 25 includes applications for:

- [1] assessment of a trial protocol
- [2] pre-registration or pre-approval assessment of data which an applicant is considering submitting to the APVMA as part of a future application for registration of a product or approval of an active constituent
- [3] any other application which requires technical assessment, and which is not covered by Categories 11–23.

2. REQUIREMENTS

When making an application under Category 25 for technical assessment of data, applicants must provide:

- one unbound copy of the combined Application Form and Overview (refer to paragraph 2.1)
- one bound copy of each of the relevant data Parts (refer to paragraph 2.2)
- a copy of the current and proposed product label if applicable
- the relevant fee (refer to paragraph 2.3).

2.1. Application Form and Application Overview

There are three different application forms for applications made under Category 25:

[1] Application for assessment of a trial protocol

The Application Form is available on the APVMA website. A single unbound copy of this form must be submitted to the APVMA.

The Application Form requires information which is relevant to a Category 25 application.

There is no Application Overview section for applications of this nature.

[2] Application for pre-registration or pre-approval assessment of data

The Application for Pre-registration or Pre-approval Assessment of Data form is available on the APVMA website. A single unbound copy of this form must be submitted to the APVMA.

The Application for Assessment form requires information which is relevant to a Category 25 application.

There is no Application Overview section for applications of this nature.

[3] Application for variation to a product and/or active constituent or a permit (not in any other Category)

The Application Form and Application Overview have been combined into a single document which is available on the APVMA website. A single unbound copy of the combined document must be submitted to the APVMA.

The Application Form requires information which is relevant to a Category 25 application.

The Application Overview section of the combined document is in the form of a template. Applicants may use this template, or may submit their own Application Overview although this must conform to the instructions and format provided in *Part 1 – Application overview* in Volume 3.

Sub-parts 1.1–1.10 of the Application Overview must **all** be completed.

2.2. Data modules

One or more of the relevant data modules (Modules 2–10) will apply for technical assessment of data that have been submitted with the application.

Further information on modules may be found in *Module levels for modular categories* in Volume 3.

2.3. Fee and timeframe

Category 25 is a modular category, therefore the fee payable and timeframe depend on which of the modules are required for assessment of the application.

The fee for a Category 25 application will always include the fee for module 1 (Screening).

The fee and timeframe for finalisation module 11.4 will apply to all applications made under Category 25.

A fee must accompany a Category 25 application. Applicants may provide the complete fee when submitting the application, or may choose to pay the screening module fee of \$460 when submitting the application and pay the remainder of the fee when requested by the APVMA, after the application has passed screening.

To calculate the timeframe assigned to an application, the longest assessment period for the specific data modules should be added to the timeframe for the relevant finalisation module.

The fee and timeframe for each application may be calculated by reference to *Module levels for modular categories* in Volume 3.

2.4. Data protection does not apply to assessment of a trial protocol or pre-approval assessment of data

Data protection is only relevant to applications made under sections 10 and 27 of the Agvet Code:

- section 10 relates to applications for approval of an active constituent, registration of a product, or approval of a label
- section 27 relates to variations to an approval or registration
 - note however that data protection does not apply to applications to vary the particulars or conditions of approval of an active constituent.

Any data submitted with an applications under Category 25 for a trial protocol assessment, pre-registration or pre-approval assessment, are ineligible for data protection at the time of submission because they are not applications for registration, approval, or variation of a registration or label approval made under Sections 10 or 27 of the Agvet Code. The APVMA does not rely on the data at the time of their submission to make a decision on approval or registration.

If data submitted for pre-registration or pre-approval assessment are subsequently submitted with an application for approval, registration or variation of an approval or registration, those data remain ineligible for protection because:

- they have been previously submitted to the APVMA
- the APVMA holds a copy of the information that is not subject to protection.

Such data must be identified in the data list for the subsequent application as 'Previously Submitted, No Protection'.

2.5. Summary data do not receive data protection

If an applicant provides a summary of data for assessment under Category 25 and later submits full data with an application for registration/variation of a product or approval/variation of an active constituent, the summary data will not receive data protection, but the full data may receive data protection if they are required and subsequently relied-on by the APVMA to grant the application.

2.6. The APVMA does not publish an application summary for Category 25 applications

The APVMA does not publish an application summary for applications made under Category 25 for a trial protocol assessment, pre-registration or pre-approval assessment because these applications are not made under Sections 10 or 27 of the Agvet Code.

2.7. A data list is required

If data are submitted with an application made under Category 25, the applicant must provide a data list, as is the case with all other applications.

Despite the fact that no application summary is published, and the data do not receive data protection, the APVMA will load the data list to its protected data database to ensure that the APVMA and the applicant have a record of what data have been submitted.

3. APPLICATION FOR ASSESSMENT OF A TRIAL PROTOCOL

3.1. The purpose of seeking the APVMA's assessment of a trial protocol

The purpose of an application under Category 25 for the APVMA's assessment of a proposed experimental trial (the trial protocol) is to provide the applicant with the APVMA's assessment of the suitability of the design of the proposed trial protocol to generate data for submission to the APVMA in support of an application for:

- registration or variation of the particulars or conditions of registration of a product; or
- approval or variation of the particulars or conditions of approval of an active constituent; or
- issue of a permit.

The most common types of trial protocol assessment are efficacy/target crop safety, or residues.

The applicant should indicate in the application for which part or parts of the APVMA's published data requirements the trial is designed to generate data.

The applicant should specify which (or all) of the issues they wish to APVMA to address in its assessment of a trial protocol, eg:

- 1 is this a valid trial design?
- 2 would results from this trial be likely to be suitable for assessment to address a specified APVMA data requirement?
- 3 would results from this trial be likely to be suitable for assessment to satisfy the Part 8 (or other data Part) requirements, in addition to any other studies that will be submitted to fulfil data requirements?
- 4 is this trial likely to fulfil APVMA expectations regarding Australian efficacy studies?

The APVMA's favourable assessment of a trial protocol does not necessarily mean that the data obtained from the trial will lead to the granting of an application. The APVMA assesses data submitted in an application for registration or approval according to relevant requirements and guidelines published in MORAG and elsewhere on the APVMA website. If the data generated from the trial do not support the application or do not contribute to a sufficient weight of evidence to support the application, the APVMA cannot grant the application.

The APVMA makes its final decision on whether to grant an application for registration or variation on the basis of consideration of a full submission of all data for all relevant data Parts, according to the criteria for granting an application provided by section 14 of the Agvet Code.

3.2. APVMA response to an application for assessment of a trial protocol

The outcome of the APVMA's assessment of a trial protocol is that the APVMA will indicate whether the proposed trial protocol is capable of generating data that are suitable for assessment by the APVMA.

If the APVMA indicates that the proposed trial protocol is not likely to be capable of generating data that are suitable for assessment, the applicant may request a meeting with the APVMA to discuss the trial protocol. This may be particularly important if the proposed trial is complex, and/or involves large numbers of crops/situations and diseases, and/or is of long duration. As an outcome, the APVMA may suggest that the applicant submit a revised trial protocol for assessment.

If the applicant subsequently follows the trial protocol which the APVMA has assessed, the APVMA will assess the resultant data on their merits.

3.3. Caveats

Applicants should seek any advice they may need on trial design and proposed statistical analysis of the resulting data, before they make an application under Category 25 for assessment of the trial protocol. The APVMA only assesses the suitability of a trial protocol for the purposes of submitting data for assessment. The APVMA does not offer advice on trial design in the same way as does a consultant.

The APVMA can only assess those aspects of the trial protocol which are submitted in the Category 25 application. If a trial protocol is silent on a particular aspect of trial design or trial conduct, the absence of APVMA comment does not mean that the APVMA has endorsed that omission from the trial's design, nor does it mean that the APVMA considers the omitted aspect of the trial's design to be irrelevant.

The applicant can proceed to conduct the trial in whichever way they choose, irrespective of the outcome of the APVMA's assessment of the trial protocol.

3.4. Statistical analysis

The APVMA recommends that applicants consult a biostatistician when designing a trial protocol. It is important that applicants ensure the statistical analysis of the data is valid for the purpose intended. This includes consideration of sample size.

For some product types, detailed guidance on statistical targets relating to safety, efficacy and residue claims is presented in the relevant chapters of Volume 3: Data requirements and guidelines, or Volume 4: Specific product guidelines.

In addition to appropriate design and conduct of trials and statistical analysis of trial data, other factors such as the circumstances in which the trial will be conducted may influence the ability to draw valid conclusions from the trial data.

The APVMA may be able to give a more accurate assessment of the statistical design of the trial protocol if the applicant has conducted a pilot trial and submits the data from that pilot trial.

3.5. Changes to the assessed trial protocol

During the conduct of the trial there may be reasons to change the assessed trial protocol. For example, while a trial design may include numbers of trial sites, replicates and controls that seem to be appropriate to demonstrate efficacy and safety, during the actual conduct of the trial, issues such as low pest or disease pressure may arise that may not produce results sufficient to demonstrate efficacy and safety of the product.

When submitting the data for assessment, the person carrying out the trials must record any changes to the trial protocol and the applicant must provide a scientific argument that outlines the reasons behind the changes, and any implications arising out of the changes.

If in doubt, the applicant should consider discussing the proposed changes and justification with the APVMA. If major deviations are to be made to the protocol, the APVMA recommends that the applicant submit to the APVMA a fresh application for assessment of the trial protocol.

The final decision on the design and implementation of the trial protocol remains the responsibility of the applicant.

3.6. Requirements

A Category 25 application for assessment of a trial protocol may include only a single product (which may contain more than one active constituent), or one active constituent if the purpose of the trial is to develop data for application for approval of that active constituent.

If the applicant wishes to generate efficacy and safety data for an active constituent in products which will be used in different situations (eg companion animals and food-producing animals, broadacre and horticulture), the applicant can either make an application for assessment of the trial to generate efficacy and safety data for one of the situations, or make a separate application for assessment of the trial to generate efficacy and safety data for each of the situations.

When making a Category 25 application for assessment of a trial protocol, applicants must provide:

- a completed Application for Assessment of a Trial Protocol, available from the APVMA website (refer to paragraph 2.1)
- the relevant fee (refer to paragraphs 2.2 and 2.3)

3.6.1. Animal Ethics Committee

Protocols which involve the use of animals, such as products which are vertebrate poisons, must include the name of the Animal Ethics Committee which the applicant will consult. The committee must be in the state or territory where the trial will be conducted.

Note that at the time of application to the APVMA for a research permit, the applicant must first have submitted a protocol for assessment by an approved Animal Ethics Committee, and must have current registration as an animal investigator in the relevant state jurisdictions.

3.7. Data modules

Example 1: An applicant requests the APVMA's assessment of a trial protocol designed to generate data on target crop efficacy and safety.

The following modules are expected to apply:

Module	Description	Fee	Statutory timeframe
Module 1	Screening	\$460	
Module 8.3	Efficacy and Safety – Level 3	\$455	3 months
Module 11.4	Finalisation – Type 4	\$145	2 months
Total fee and statutory timeframe:		<u>\$1,060</u>	<u>5 months</u>

The APVMA may apply more than a single Module 8.3 for complex trial protocols which encompass more than one discipline. For example, an applicant might intend to use a complex or novel statistical method to analyse results and the APVMA must assess both the trial design and the statistical methodology.

Example 2: An applicant requests the APVMA's assessment of a trial protocol designed to generate residues data.

The following modules are expected to apply:

Module	Description	Fee	Statutory timeframe
Module 1	Screening	\$460	
Module 5.5	Residues – Level 5	\$1,070	3 months
Module 11.4	Finalisation – Type 4	\$145	2 months
Total fee and statutory timeframe:		<u>\$1,675</u>	<u>5 months</u>

4. APPLICATION FOR PRE-REGISTRATION OR PRE-APPROVAL ASSESSMENT OF DATA

The purpose of a Category 25 application for pre-registration or pre-approval assessment of data is to enable an applicant to submit only a single data Part which may be contentious, so that if the APVMA does not give a favourable assessment of that data Part and advises that it would not grant an application for registration of a product or approval of an active constituent as the case may be, the applicant is saved the trouble and expense of submitting the other data Parts which are required for an application. Alternatively, the applicant may choose to generate additional or fresh data to overcome the deficiencies of the data Part.

4.1. Full data

The APVMA will apply the same assessment module that would have applied if the data had been submitted as part of an application for registration of a product or approval of an active constituent.

If the APVMA's assessment is favourable, those data need not be re-submitted when the applicant subsequently submits the application for registration of a product or approval of an active constituent as the case may be.

Note: Data submitted under Category 25 do not receive data protection (refer to paragraph 2.4).

If the applicant makes changes to the proposed product or label between a pre-registration assessment of data and the actual application for registration or approval, the APVMA may require additional assessment and/or information.

4.2. Summary data

The applicant may decide to submit a summary of data which they propose to later submit as part of an application for registration of a product or approval of an active constituent. The APVMA will assess the summary data to determine whether sufficient data seem to be available for assessment of the full data when they are later submitted with an application for product registration or active constituent approval, as the case may be.

Refer to paragraph 2.5 for information relevant to data protection and summary data.

4.3. Example

Example: An applicant is considering whether to make an application to extend the efficacy claims of an existing broadacre herbicide, to include new weed species. The applicant is concerned that the APVMA may not agree that the trial data demonstrate the efficacy of the product. The applicant submits Part 8 data for pre-application assessment.

The following modules are expected to apply:

Module	Description	Fee	Statutory timeframe
Module 1	Screening	\$460	
Module 8.1	Efficacy and safety – Level 1	\$1,695	5 months
Module 11.4	Finalisation – Type 4	\$145	2 months
Total fee and statutory timeframe:		<u>\$2,300</u>	<u>7 months</u>

4.4. Fee and timeframe

See paragraph 2.3.

4.5. Data protection

See paragraph 2.4.

Revision history

Revision date	Description of revision
1 July 2005	First edition
1 October 2005	Second edition <ul style="list-style-type: none"> data protection paragraph 2.4 added.
1 April 2006	Third edition <ul style="list-style-type: none"> paragraph 3: added caveat regarding results obtained from trials paragraph 3.2.1: added note that animal experimenters must be registered/licensed.
1 September 2007	Fourth edition <ul style="list-style-type: none"> change title to make the intent of a Category 25 application more clear paragraph 2.1: removed the requirement to fill out the Application Overview because there is no Application Overview in the application form; differentiated the different types of application which are assessed under Category 25 paragraph 2.4: data protection does not apply to applications for assessment of a trial protocol, nor pre-registration assessment of data paragraph 3: changed the emphasis for assessment of a trial protocol from external reviewers to the APVMA; emphasised that the APVMA will only comment on aspects of a trial protocol which are presented to it; clarified the purpose and limitations of a trial protocol assessment add new paragraph 4 and sub-paragraphs add an additional example extensive revision to other text.