

**Category 1 application**

**Approval of a new active constituent  
contained in a chemical product,  
registration of the associated chemical  
product and approval of the product label**

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## 1. DEFINITION

Schedule 6 of the Agvet Code Regulations describes a Category 1 application as:

*Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring a full assessment of the active constituent and chemical product.*

A full<sup>1</sup> assessment is where a comprehensive assessment of data for both the active constituent/s and the product is required for the following data Parts:

- Chemistry and Manufacture data for both the active constituent and the product Part 2
- Toxicology data for both the active constituent and the product including poisons scheduling Part 3
- Metabolism and Kinetics Part 4
- Residues and Trade Part 5
- Occupational Health and Safety Part 6
- Environment Part 7
- Efficacy and Safety Part 8

Where applicable, the following data may also be required:

- Other Trade Aspects Part 9
- Special Data Requirements Part 10

Note: The Parts relate to Volume 3: Data requirements and guidelines.

The following are examples of applications which would be assessed under Category 1:

- a new chemically-synthesised active constituent and a product containing that active constituent for use as a fungicide on citrus
- a new chemically-synthesised active constituent and a product containing that active constituent for use as a pre-emergence herbicide in cotton.

The list of data studies for a full (comprehensive) assessment may be determined by reference to *Module levels for modular categories* in Volume 3. The studies required for Category 1 applications are described in Level 1 of the relevant modules.

Further information on data requirements and guidelines is provided in Parts 1–10 of Volume 3.

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<sup>1</sup> A full product assessment for Category 1 is equivalent to the following modules in Schedule 7 of the Agvet Code Regulations: Modules 1, 2.1, 3.1, 4, 5.1, 6.1, 7.1, 8.1, 11.1 and 12.

## 1.1. Agricultural products which do not require a Category 1 application

Some products which contain a new active constituent will not require all the assessments undertaken in a full (comprehensive) assessment and may be eligible for assessment under Category 2. Examples are:

- products which are not proposed for use on crops for human food or animal feed
- products which contain an active constituent which has not been approved by the APVMA, but which has been assessed and approved by another Australian regulatory authority eg National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Therapeutic Goods Administration (TGA).

Category 2 is a modular category which allows reduced levels of assessment (as appropriate) for the data Parts listed above. For further information see the Category 2 chapter in this volume.

## 2. REQUIREMENTS

When making a Category 1 application for active constituent approval and registration of a new product, applicants must provide:

- one unbound copy of the combined [Application Form and Overview](#) (refer to paragraph 2.1 and also Part 1 of Volume 3)
- one bound copy of each of the relevant data Parts (refer to paragraph 2.2 and also Parts 2–10 of Volume 3)
- the product label (refer to paragraph 2.3)
- the relevant fee (refer to paragraph 2.4)
- a data list (refer to paragraph 2.6).

### 2.1. Combined Application Form and Overview

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 provided to the APVMA.

The **Application Form** is divided into separate sections for application for registration of the product and approval of the active constituent.

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

Data requirements for Category 1 applications are identical to Modules 1, 2.1, 3.1, 4, 5.1, 6.1, 7.1, 8.1, 11.1 and 12 as detailed in *Module levels for modular categories* in Volume 3. Where applicable, Modules 9 and 10 may also be required.

A single data dossier must be provided with the initial application. Once the application passes administrative and technical screening the APVMA will request additional copies of the data dossier, including the Application Form and Overview.

## 2.3. Label

Applicants must provide a label with the Application Form and Overview. The APVMA recommends that the label be in draft form so that it can be amended if necessary, however applicants may choose to submit the marketed product label (MPL).

Applicants may provide the draft label as either:

- two copies of the text label (TXL) printed on paper; or
- an e-label on CD. The CD must be attached to the Application Form and Overview and not submitted separately or by email.

The draft label must include all label components ie primary pack, immediate container and leaflet, as relevant.

All parts of the draft label must be in accordance with the latest editions of the:

- *Labelling Code*; and
- *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP); and
- *Handbook of First Aid Instructions and Safety Directions* (FAISD Handbook).

After the APVMA has assessed the draft label and is satisfied that the label is acceptable, the APVMA will ask the applicant to provide an e-label of the MPL for approval. If the MPL is acceptable and all other matters relevant to the application are acceptable, the APVMA will approve the label and grant the application.

Refer to *Label Approval Process* in Volume 5 for further information.

## 2.4. Fee and timeframe

The fee for a Category 1 application is \$48,860.

The timeframe is 15 months.

## 2.5. Public consultation

Prior to approval of the active constituent and registration of the product, the APVMA will conduct a round of public consultation. This is normally by means of publication of a Gazette Notice called a Public Release Summary (PRS) which invites comment on the APVMA's intention to approve the active constituent and register the product.

If the product is intended for use in crops that will result in residues in food or animal commodities, the APVMA will normally also publish a Trade Advice Notice (TAN), inviting comment.

## 2.6. Data protection

Data protection applies for all applications which are assessed under Category 1 where the applicant is providing data to the APVMA that are eligible for protection. Publicly available data are ineligible for protection.

Applicants must provide a data list, including an entry for all information that meets the definition given on the APVMA website data protection page at [http://www.apvma.gov.au/registration/data\\_protection.shtml](http://www.apvma.gov.au/registration/data_protection.shtml). This requirement applies irrespective of whether an application is eligible for data protection.

# 3. GUIDELINES

## 3.1. Secondary applications

When applications are simultaneously submitted to the APVMA for registration of more than one new product containing new active constituents, one product application may be assessed as the primary application and the others as secondary applications.

A secondary application exists when an applicant has another product containing the same active constituent/s as the primary product undergoing registration at the same time, and the assessment of some of the data for the first product can be used for both products. The product requiring the highest level of assessment should always be presented as the primary application.

Where the method of application and use pattern are the same, the product with the highest concentration or application rate should be the subject of the primary application. Where applicable, the primary application will be assessed under Category 1 whereas the secondary applications, involving modular assessments of data that are not common with the primary application, can be assessed under Category 2. Secondary applications will only be finalised once the primary product application is finalised.

## Revision history

Revision date	Description of revision
1 July 2005	First edition
1 October 2005	Second edition <ul style="list-style-type: none"><li>hyperlinks inserted to Labelling Code, SUSDP and FAISD Handbook.</li></ul>
1 April 2006	Third edition <ul style="list-style-type: none"><li>paragraph 2: added reference to data list.</li></ul>
1 July 2007	Fourth edition <ul style="list-style-type: none"><li>paragraph 2.3: revised label requirements</li><li>minor text changes</li></ul>