

Category 6 application

Registration of a new chemical product that is closely similar to a registered chemical product: Chemistry and manufacture data required

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1. DEFINITION

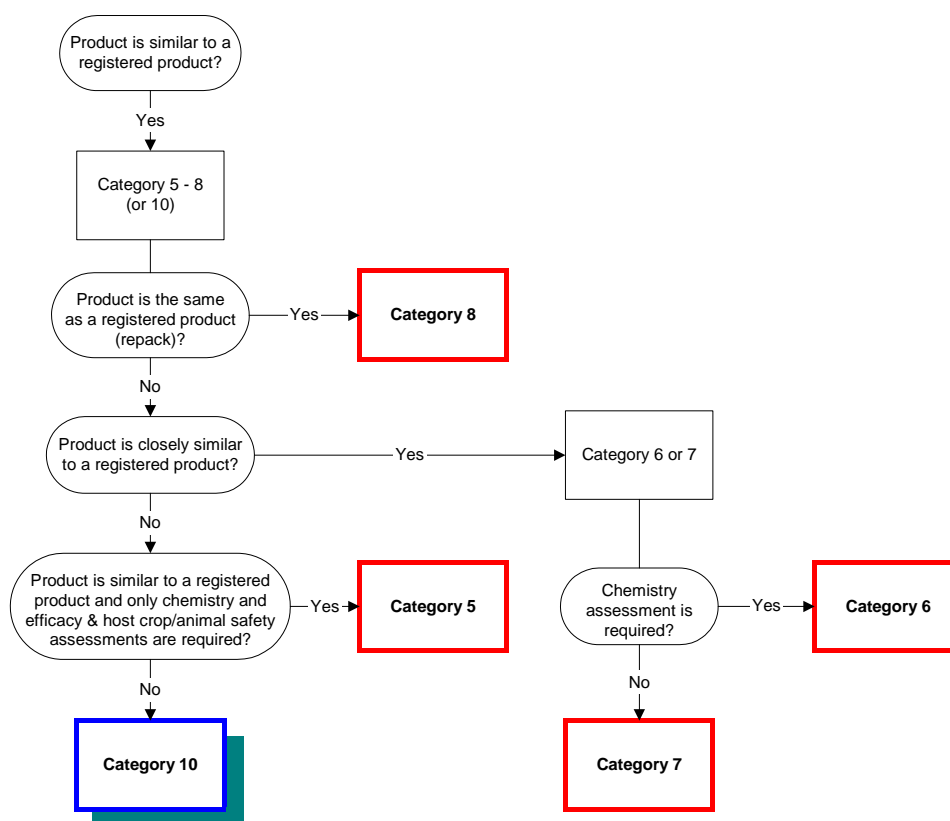
Schedule 6 of the Agvet Code Regulations describes a Category 6 application as:

Application for registration of a chemical product containing an approved active constituent and approval of the product label if:

- (a) *the chemical product is closely similar to a registered chemical product; and*
- (b) *efficacy and safety data are not required to demonstrate the similarity of the chemical product to the registered chemical product; and*
- (c) *chemistry and manufacture data are required.*

Category 6 applications do NOT require technical assessment of any data other than chemistry and manufacture because the formulation and use pattern of the reference and proposed product are closely similar, and the products would be expected to be equivalent in terms of their efficacy and host crop safety, residues and trade, environmental safety, human health and occupational health and safety aspects.

The criteria for a product to be considered closely similar to a reference product and eligible for assessment under Category 6 (see paragraph 1.1) are less stringent than those required for Category 7, but more stringent than those for Category 5. For example, if in addition to the criteria in paragraph 1.1, the proposed and reference products have the same formulators and immediate container packaging materials and closure system, chemistry data would not be required and the application may be eligible for assessment under Category 7. The flowchart below shows how an application may fit into categories 5, 6, 7, 8 or 10:



1.1. Definition of closely similar agricultural products

Applications to register new products under Category 6 are those where the formulation and label instructions of the new product are closely similar to those of a registered reference product, and only Part 2 chemistry and manufacture data to demonstrate product quality are required.

Applications to register new products under Category 6 do not require demonstration of target crop/situation efficacy and safety or biological equivalence provided they are considered to be closely similar to a registered reference product.

For a new product to be considered closely similar to a registered reference product, the new product must meet all of the following criteria:

- the active constituents must be the same and be approved by the APVMA
 - ie the source or manufacturer must appear on the Record of Approved Active Constituents at:
http://www.apvma.gov.au/actives/downloads/aa_AK.pdf
 - if an active constituent is not present on the Record of Approved Active Constituents, the APVMA may not need to approve separate sources. For further details on approval of active constituents, applicants may contact the APVMA's Chemistry and Residues Program on 02 6210 4818
- the active constituents must be the same concentration
- other constituents in the formulation may be different from those in the reference product but must perform similar functions (eg emulsifier, surfactant, dye, solvent)
- the formulation type must be the same
- the label must have the same crops/situations and pests (ie no additional uses) and must include similar use and precautionary/safety instructions
 - however, there may be fewer or reduced claims compared to the reference product.

Examples of product types which may be eligible for assessment under Category 6 include products which are closely similar to the reference product, but fall outside the definition of Category 7 due to differences which may include:

- differences in non-active constituents.

If the APVMA determines that the proposed product is not closely similar to the nominated reference product (eg due to differences in the formulation or label instructions or uses), additional data and assessments may be required. In this case the applicant will be informed that the application is outside the scope of Category 6 and application under a different category is required. For example, if in addition to chemistry and manufacturing data, efficacy or host crop safety data are required to demonstrate similarity to the reference product, the application may be assessed under Category 5. If the formulation or label instructions/uses are significantly different and require other types of assessment (eg toxicology, residues and trade, OHS or environment), the application would be assessed under Category 10.

Applications to register closely similar products which contain a new source of active constituent are ineligible for assessment under Category 6. Such applications, which require approval of the new source of active constituent, may be assessed under modular Category 24.

1.2. Reference product

A reference product is a chemical product which is registered under Part 2 of the Agvet Code, and has an approved label. It does not include a product for which the registration has been cancelled or a product which is the subject of an application for registration.

If an applicant nominates a reference product for which registration has been stopped or cancelled, the application would be ineligible for Category 6 and may be assessed under modular Category 10.

Where possible the original pioneer product should be used as the reference product for Category 5 applications.

2. REQUIREMENTS

When making a Category 6 application for registration of a new product, 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)
- the product label (refer to paragraph 2.3)
- the relevant fee (refer to paragraph 2.4).

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** requires information which is relevant to a Category 6 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-part 1.1 must include details of the reference product.

Applicants must provide a statement under the appropriate heading with brief argument why data are not required for each sub-part 1.3–1.10.

2.2. Data

Data requirements for Category 6 applications are as follows:

Description	Data Part	Equivalent* module level
Chemistry and Manufacture	Part 2	Module 2.3

* Category 6 is a fixed category for which the fee and timeframe are predetermined. Although Category 6 is not a modular category, the chemistry and manufacture data required correspond with those described for a Module 2.3 assessment in *Module levels for modular categories* in Volume 3.

Detailed Part 2 data requirements can be determined by reference to Volume 3: Data requirements and guidelines.

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 6 application is \$2,245.

The timeframe is five months.

2.5. Data protection

Data protection applies for all applications which are assessed under Category 6, 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 for chemistry and manufacture data. This requirement applies irrespective of whether an application is eligible for data protection.

Further information is available on the APVMA website data protection page at http://www.apvma.gov.au/registration/data_protection.shtml.

Applicants under Category 6 may need to refer to data relied on by the APVMA to register the reference product. The reference product may also have required access to protected data in relation to the active constituents or its reference product. Where the Category 6 applicant is not the authorising party for the data used to approve the active constituents or register the product, the applicant must obtain consent for use from the relevant authorising parties. Applicants can determine whether they are using protected data by checking the product details on the product search facility on the APVMA website.

3. EXAMPLES

Example 1: Application is made for registration of a new product for use as an adjuvant (eg wetter, spreader, sticker, penetrant), of the same formulation type and containing an approved active constituent at the same concentration as the reference product, with the same label claims and instructions, including application rates. Other formulation constituents may vary slightly.

An application of this nature would be assessed under Category 6 because only chemistry data would be required.

Example 2: Application is made for registration of a new product for use as an insecticide in a wide variety of crop and non-crop situations, of the same formulation type and containing an approved active constituent at the same concentration as the reference product, with fewer label claims, but other instructions being the same. The product is closely similar to the reference product in concentration and types of non-active constituents used.

An application of this nature would be assessed under Category 6 because the new product does not necessarily have to be registered for every use that is nominated on the reference product. However, adding uses that are not on the label of the reference product would take the application out of Category 6.

Example 3: Application is made for registration of a new product for use as a fungicide in pome, stone and various other fruit crops, of the same formulation type and containing an approved active constituent at the same concentration as the reference product, with the same label claims and instructions. The product differs from the reference product in the concentration and types of surfactants used.

An application of this nature would not be assessed under Category 6 because the differences in formulation could change the risks associated with the product and its efficacy. Category 5 is the most appropriate category.

Example 4: Application is made for registration of a new product for use as a post-emergent selective herbicide, containing an approved active constituent at the same concentration as the reference product, with the same label claims and instructions. However, the non-active constituents vary such that the formulation type has changed.

An application of this nature would not be assessed under Category 6 because toxicological and OHS assessments would be required in order to set appropriate safety directions. The applicant would be required to apply under Category 10 with the appropriate modules to cover the different assessments required.

Example 5: Application is made for registration of a new insecticide product containing a new source of an approved active constituent at the same concentration as the reference product, with similar non-active constituents, the same formulation type, and the same label claims and instructions.

An application of this nature would not be assessed under Category 6 because the new source of active constituent requires approval. Application under modular Category 24 would be appropriate.

Revision history

Revision date	Description of revision
1 July 2005	First edition
1 October 2005	Second edition <ul style="list-style-type: none"> reference product (paragraph 1.2): paragraph now refers correctly to Category 6 instead of Category 5 hyperlinks inserted to Labelling Code, SUSDP and FAISD Handbook.
1 April 2006	Third edition <ul style="list-style-type: none"> paragraph 1.1: moved paragraph from 1.2 on products not closely similar paragraph 1.2: added statement that a product which is the subject of an application for registration cannot be a reference product paragraph 2.5: changed reference to data list.
1 July 2007	Fourth edition <ul style="list-style-type: none"> paragraph 1.1: edit to clarify the definition of 'similar' with respect to active constituents paragraph 2.3: revised label requirements paragraph 2.5: edited to state that applicants must provide a Data List for chemistry and manufacture data minor text changes.
1 October 2007	Edition 4.1 <ul style="list-style-type: none"> paragraph 1.1: correct an error made in edition 4, in which a reference that the concentration of active constituents must be the same, was omitted.