

Category 15 application
Approval of a new active constituent:
Comprehensive assessment

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1. DEFINITION

Schedule 6 of the Agvet Code Regulations describes a Category 15 application as:

Application for approval of an active constituent requiring a full assessment.

A Category 15 application is for approval of a new active constituent, where a full¹ (comprehensive) assessment is required of chemistry and toxicology data.

1.1. Application types

Applications assessed under Category 15 are those where the active constituent has not been previously approved by the APVMA and meets any of the following criteria:

- an active constituent manufactured by chemical synthesis
 - a highly purified and well-characterised active constituent derived from plants or animals (however, see 1.2)
 - a semi-synthetic active constituent manufactured by the chemical modification of a highly purified and well-characterised intermediate derived from plants or animals (however, see 1.2)
 - a semi-synthetic active constituent manufactured by the chemical modification of an intermediate produced by conventional fermentation (however, see 1.2)
 - an active constituent produced by conventional fermentation or using recombinant DNA technology (however, see 1.2)
 - an active constituent produced by transgenic technology
 - growth regulators, antibiotics* and polypeptides
 - some animal tissue extracts and some plant extracts/oils (however, see 1.2).
- * all new antibiotics will require submission of special data (Part 10) which involves antibiotic resistance risk assessment for both the active constituent and the product, as part of a separate application for product registration.

¹ A full assessment of an active constituent under Category 15 is equivalent to either of the following pairs of modules in Schedule 7 of the Agvet Code Regulations: Modules 2.1 and 3.1; or 2.1 and 3.2.

1.2. Active constituents which require only limited toxicological assessment

If an active constituent requires a limited toxicological assessment, it may be eligible for assessment under Category 16.

This applies to most biological active constituents.

It also applies to any other active constituent for which an acceptable comprehensive toxicological assessment report has been provided. In order to be acceptable, comprehensive toxicology reports must be of a quality acceptable under the Organisation for Economic Co-operation and Development (OECD) and dated from 1 July 2005.

2. REQUIREMENTS

When making a Category 15 application for active constituent approval, 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 relevant fee (refer to paragraph 2.3)
- a data list (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** 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 1.1–1.4 of the Application Overview must all be completed.

2.2. Data

Data requirements for Category 15 applications are as follows:

Description	Data Part	Equivalent module level
Application Overview	Part 1	
Chemistry and Manufacture data for the active constituent	Part 2	Module 2.1
Toxicology data for the active constituent, including drugs and poisons scheduling	Part 3	Module 3.1 or Module 3.2 Module 4
Metabolism and Kinetics	Part 4	

Category 15 is a fixed category for which the fee and timeframe are predetermined. Although Category 15 is not a modular category, the chemistry and manufacture and toxicology data required correspond with modules described in *Module levels for modular categories* in Volume 3.

The toxicology data required for a Category 15 application correspond with those described for a Module 3.1 assessment (where the active constituent is intended for a food-producing use) or a Module 3.2 assessment (where the active constituent is intended for non-food-producing use) in *Module levels for modular categories* in Volume 3.

Details of Part 2, Part 3 and Part 4 data requirements can be seen by referring to Volume 3: Data requirements and guidelines.

The APVMA seeks advice from the Office of the Gene Technology Regulator (OGTR) on any application for approval of a genetically modified organism (GMO) or the product of a GMO. If the APVMA assesses an active constituent which is a GMO under Category 15, the applicant must address the OGTR's requirements.

Imported biological agents require a permit from the Australian Quarantine and Inspection Service (AQIS) before they can be imported into Australia.

2.3. Fee and timeframe

The fee for a Category 15 application is \$23,430.

The timeframe is 12 months.

2.4. Data protection

Data protection applies for all applications which are assessed under Category 15 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. This requirement applies irrespective of whether an application is eligible for data protection.

Revision history

Revision date	Description of revision
1 July 2005	First edition
1 October 2005	Second edition <ul style="list-style-type: none">paragraph 2.2: reference to data Part 10 removed.
1 April 2006	Third edition <ul style="list-style-type: none">paragraph 2: added reference to data list.
1 July 2007	Fourth edition <ul style="list-style-type: none">minor text changes.