



## **Operational notice**

### **The APVMA's approach to management of defects in Category 7, 6 and 5 applications for registration of a new product**

#### **Use of Categories 7, 6 and 5**

Category 7 is for application for registration of a new product which is closely similar to an existing registered product, called the 'reference product'. There are no data requirements for an application made under Category 7.

Category 6 is for application for registration of a new product which is closely similar to a reference product, but there are sufficient differences between the applicant product and the reference product, that chemistry and manufacture data are required to support registration of the product.

Category 5 is for application for registration of a new product which is similar to a reference product, but there are sufficient differences between the applicant product and the reference product, that chemistry and manufacture data, and efficacy and target crop/animal safety data are required to support registration of the product.

#### **Definition of 'closely similar' and 'similar': Relevant application category**

Schedule 6 of the Agvet Code Regulations sets out the criteria by which agricultural and veterinary products are judged to be closely similar to, or similar to, a reference product. Ag MORAG and Vet MORAG provide further detail on the definitions of 'closely similar' and 'similar'.

The APVMA sometimes receives Category 7, or 6, or 5 applications for registration of a new product, where the proposed product does not fit all the criteria for acceptance of the application under Category 7, or 6, or 5 as the case may be.

Common reasons include:

- the active constituents or concentration of active constituents differ from the reference product.
- the formulation is not closely similar to, or similar to, the reference product
- the non-active constituents of the product differ from the reference product.

Application for registration of a new product which does not fit the criteria of Category 7 should be made under Category 6, or Category 5, or Category 10 depending on the nature of the proposed product.

Similarly, application for registration of a new product which does not fit the criteria of Category 6 should be made under Category 5 or Category 10, and an application which does not fit the criteria of Category 5 should be made under Category 10.

### **Application made under an incorrect application category**

It is the responsibility of the applicant to ensure that the particulars of the product for which an application for registration is being made under Category 7, 6 or 5, meet the criteria set out in Schedule 6 and in MORAG.

If the particulars of the product do not meet these criteria, the APVMA will issue a notice to the applicant to say that the application contains defects. In this notice, the APVMA will cite which of the following defects the application contains, relevant to the category of the application:

- the identity and/or concentration of the active constituent is/are not the same as the reference product;
- the non-active constituents are not the same or do not perform similar functions to the reference product [ag products], or are not equivalent to the reference product [vet products];
- the formulation type is not the same as the reference product;
- the proposed use pattern and use instructions are not the same as the reference product;
- the label claims are not the same, or are not reduced, compared to the claims of the reference product
- product specifications are not the same as the reference product [vet products];
- the site of manufacture is not the same as the reference product [vet products].

Exact details of the defects will be with reference to Schedule 6 of the Agvet Code Regulations and MORAG.

The APVMA will not provide details of any differences between the proposed chemical product which is the subject of the application, and the reference product, because this may inadvertently release commercially confidential information.

If the application does not satisfy the criteria for Category 7, 6 or 5 the applicant may:

- request the APVMA to amend the application to the correct application category; or
- withdraw the application and make a new application under the correct application category, which includes the relevant data and fee.

### **The APVMA will not accept certain requests to amend the application**

[1] The APVMA will not accept a request to amend an application made under Category 7, 6, or 5, to modify the formulation or formulation type of the proposed product.

- if the applicant wishes to modify the formulation or formulation type of the proposed product, the applicant must withdraw the application and submit a new application.

[2] The APVMA will not accept a request to amend an application made under Category 7, 6, or 5, to change the reference product.

- if the applicant wishes to change the reference product, the applicant must withdraw the current application and submit a new application.

**If the applicant cannot rectify the defects in the application:**

If the applicant cannot rectify the defects in the application by the due date contained in the defects notice, it is open to the applicant to:

1. Provide a valid reason why the APVMA should accept the application under Category 7, 6 or 5 as the case may be; or
2. Request the APVMA to defer consideration of the application until a specified date at which time the required information will be available; or
3. Inform the APVMA that they wish to withdraw the application.

If the applicant withdraws the application, or if the APVMA rejects the application, or treats the application as having been withdrawn, any data submitted with the application will not be eligible for data protection for this application nor any other application.

**Applicants may only select a single reference product**

All of the APVMA's guidelines refer to 'the reference product' or 'a reference product'. This phraseology implies that the applicant may select only a single reference product, but the APVMA has not made this explicitly clear.

From the date of this notice, applicants may select only a single reference product for any application for which a reference product is relevant.

**Refund of fees**

If the APVMA rejects an application, or treats an application as having been withdrawn, or if the applicant withdraws an application, the APVMA will refund any fee paid by the applicant in respect of the application, other than the preliminary assessment fee of \$460.

APVMA January 2008