

## **THE APVMA SCREENING OF APPLICATIONS**

The APVMA will undertake a preliminary assessment of an application to assess whether the application meets all the requirements as prescribed by the legislation.

If all the requirements are met the APVMA will notify the approved person that the application has passed the preliminary assessment and that a full evaluation of the information submitted will proceed.

If the preliminary assessment determines that there are deficiencies in the application but that these deficiencies can reasonably be rectified the APVMA will notify the approved person of these deficiencies. The APVMA will also specify the timeframe in which the applicant is to rectify the deficiencies.

If the deficiencies are not addressed within the period required the APVMA may defer consideration of the application or treat the application as having been withdrawn. If so it will notify the approved person of its decision.

If the preliminary assessment determines that there are deficiencies in the application but that these deficiencies cannot reasonably be rectified the APVMA may reject the application.

If the APVMA rejects the application it will notify the approved person of this decision and give reasons for its decision. A screening fee is retained by the APVMA however monies paid in excess of the screening fee are repaid.

### **The screening process**

All applications for new products are recorded onto a database as soon as they arrive at the APVMA, after which they are given a unique number that becomes, when registration is granted, the National Chemical Registration Information System Database (NCRIS) number. This number always remains with the product application after it is registered. Another number relative to each application is used; this is the Application Tracking System (ATS) number. Over the life of a product several applications for registration particulars or labels may be made and the APVMA uses the ATS number to identify each application individually. On all correspondence to the applicant or approved person, both numbers will be quoted. Please quote both numbers when corresponding with the APVMA.

The screening process has two separate steps:

- administrative; and
- technical/agency.

### **Administrative screening**

The Registration and Client Services Team (RCS) processes applications through an administrative screen as soon as they are received by the APVMA. RCS also records accompanying bound data and receipts all monies received.

The information checked in administration screening are for the:

**Applicant details:**

- has a covering letter been supplied?
- is the applicant an individual or a body corporate? Has an ACN; ARBN or an overseas equivalent number been provided? Is the Australian applicant also the approved person?
- if not, has the Australian applicant authorised a different person as the approved person? Is the authorisation of the format required?
- for overseas applicants has an approved person been authorised to deal with the application? Is the authorisation of the format required?
- is the application form signed and dated by the approved person? Is the signature an original signature?
- has a fully completed application form been supplied, including the formulation details and the formulators details and letters of support?
- is the information supplied legible, typed or written in pen, without any correction fluid used?
- if the application is to vary an existing registered product or label, are the registrants details provided the same as those on the APVMA register?

**New product details:**

- if the applicant is not the manufacturer of the active constituent is a letter of support from the manufacturer of the active constituent provided?
- for new products similar to registered products has a registered reference product been nominated?
- for applications to repack a registered product under a new name, has a registered reference product been nominated? Is the formulator of the product the same as the reference product? Has a letter of support been provided by the formulator?
- have two copies of the product label been provided?

**Variation to existing product details**

- if the application is to vary an existing registered product or label, is the product name on the application form the same as on the APVMA register?
- if the application is to vary a label have two copies of the product label been provided?

Applications will either pass or fail an administrative screen. If an application passes the administrative section of screening, it progresses to the next level, technical/agency screening. The APVMA will forward a letter to the approved person notifying them that the application has been received. If an application fails administrative screen a deficiency letter will be sent outlining what is required and the timeframe within which the requested information must be supplied. Once the requirements are met the application will progress to technical/agency screening. If the relevant information is not supplied within the timeframe and the applicant or approved person has not requested an extension in the timeframe to supply the required information the APVMA will advise the approved person that they have a further 28 days to comply with the APVMA's requirement and that if they do not

contact the APVMA within that time it will treat the application as having been withdrawn.

### **Technical/agency screening**

The Agricultural, Veterinary, and Agency evaluators meet on a weekly basis to screen new applications and deal with responses to deficiencies that they had identified to the applicant when they first screened an application. The evaluators will screen the applications against the technical requirements outlined in the Ag Requirements Series and the Vet Requirements Series and determine whether the data/information meet the type of application proposed and whether the correct fee has been provided.

### **APPLICATIONS THAT MEET THE APVMA's REQUIREMENTS**

If the application passes the technical and agency screen it will be assigned to an evaluator. In this situation, the APVMA may request additional copies of data to allow the technical review to commence. The timeframe for assessment (that is the APVMA's "clock") commences the day the application passes screening, or if additional copies of data and/or fees are requested the date the APVMA receives the data and/or fees.

### **APPLICATIONS THAT DO NOT MEET THE APVMA's REQUIREMENTS**

#### **Applications which have deficiencies which can be reasonably easily rectified**

If the application fails technical and/or agency screening the APVMA will outline the deficiencies in the application in a letter to the approved person. The letter will include the timeframe within which the requirements must be met.

The deficiency letter will contain a contact for general queries (regarding the registration process) and a contact for any technical queries (regarding the deficiencies outlined in the correspondence). All correspondence/queries should be directed to the relevant contact officer. All queries of a technical/regulatory nature must be in writing.

The approved person is required to supply all requested information within two (2) months of receiving a deficiency letter. The following paragraphs describe the APVMA's policy on processing the applications for which it has or has not received the information requested from the approved person.

#### **Full response**

A full response to a deficiency letter means that the approved person has provided either data or relevant scientific argument to address each of the deficiencies identified by the APVMA. If the technical and/or agency evaluators determine that the information in the response now means that all the APVMA's requirements have been met then the application will proceed to evaluation.

However the technical and/or agency evaluators may determine that the information in the response is not sufficient to address the APVMA's requirements in which case the application remains deficient and a further deficiency letter is sent to the approved

person. An application will not pass screening until all deficiencies have been addressed to the satisfaction of the APVMA.

### **Partial response**

A partial response to a deficiency letter means that the approved person has provided data or relevant scientific argument to address some but not all the deficiencies identified by the APVMA. A letter will be sent to the approved person reminding them of all outstanding requirements and inform the applicant or approved person of the timeframe that is remaining to address the remaining issues. The application will be allocated a “Level One” status.

If no response is received to the reminder letter or the second response is incomplete (a partial response is received) the application will be allocated a “Level Two” status and a letter will be sent to the approved person reminding them again of the outstanding requirements. The letter will also inform the approved person that there is one “Level” left to complete the submission.

If no response is received or a third response is incomplete (a partial response is received) the APVMA will treat the application as having been withdrawn due to “failing level three”. A letter to this effect will be sent to the approved person. \$620.00 of the application fee will be retained by the APVMA and the remainder of the application fee, if any, will be refunded.

If the APVMA receives the remaining required information for an application at level one or two and the technical and/or agency evaluators determine that the information in the response now means that all the APVMA’s requirements have been met then the application will proceed to evaluation.

### **No response to a deficiency letter**

If the approved person does not respond within the two- (2) month timeframe they will automatically accumulate “Level One and Two” status. A letter will be sent to the approved person giving the approved person 28-days to respond to the APVMA’s requirements. If a response is not received to the 28-day letter the APVMA will treat the application as having been withdrawn due to “failing level three”. A letter to this effect will be sent to the approved person. \$620.00 of the application fee will be retained by the APVMA and the remainder of the application fee, if any, will be refunded.

### **Extension of time**

Requests for extensions of time to address APVMA’s requirements will be accepted in writing from the approved person only; it is important to outline what you will do to rectify each deficiency, and you must nominate the anticipated finish date. Extensions of time to rectify deficiencies will be assessed on the merits of each application.

### **Applications where deficiencies cannot be reasonably easily rectified**

If the preliminary assessment determines that there are deficiencies in the application but that these deficiencies cannot reasonably easily be rectified the APVMA may reject the application.

If the APVMA rejects the application it will notify the approved person of this decision and give reasons for its decision. \$620.00 of the application fee will be retained by the APVMA and the remainder of the application fee, if any, will be refunded.

### **OBLIGATION TO NOTIFY THE APVMA OF ANY RELEVANT NEW INFORMATION RELATING TO A PENDING APPLICATION**

If an application for approval of an active constituent or registration of a chemical product has been lodged with the APVMA and the applicant becomes aware of any relevant information in relation to the constituent, or in relation to the product or and of its constituents, that person must give that information to the APVMA.

Relevant information includes information:

- that contradicts any information given to the APVMA; and/or
- shows that the use of the constituent or product may be a risk to public health, environment, plants or animals or shows that the product may not be effective.

The information must be given in writing and be signed by an approved person.

Applicants or the appointed approved person will be reminded of their obligation to notify the APVMA of any relevant new information when submitting an applications (ie on the application form) and in all correspondence between the APVMA and the applicant or the appointed approved person.

## Section 11A screening process

