Australian Government

Australian Pesticides and Veterinary Medicines Authority

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Contestability of the efficacy assessment

A pilot to determine the effectiveness of applicants providing completed efficacy assessments with submission of registration or variation applications.

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The Manager, Public Affairs
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604 Australia

Telephone: +61 2 6210 4701

Email: communications@apvma.gov.au.

This publication is available from the APVMA website: www.apvma.gov.au.

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1.1 What is contestability?

Through the efficiency through contestability programme, the Australian Government is assessing its functions to determine if performance can be improved through alternative structures, processes or provider arrangements. Contestability encourages Commonwealth entities to adopt a more commercial mindset and seek ways of improving the performance of existing or proposed government functions (further details available from the Department of Finance website)

www.finance.gov.au/resource-management/governance/contestibility/overview

Contestability shifts the emphasis from the function to be carried out to the desired outcome government seeks to achieve.

1.2 What are we doing?

The APVMA is trialling a process to see if it is possible to move the function of conducting or commissioning a data assessment from the APVMA to the private sector while retaining the outcome of quality decisions for registration or variation applications. At the same time, this will be a test of the market to determine whether there are enough providers for the vast range of application types the APVMA assesses and whether the regulated agvet industry is interested in a process change of this kind.

1.3 Why are we doing it?

Contestability is a whole of government initiative aimed at moving towards a smaller, more nimble government. Contestability looks at using the private sector to deliver certain services at the same standard for a reduced cost.

Moving the function of conducting or commissioning data assessments from the APVMA to alternate private sector providers has the potential to:

- provide applicants with more control regarding data assessment timeframes and costs
- reduce administrative processes within the APVMA
- increase the efficiency of application processing
- open the area of data assessment to competition.

1.4 How are we doing it?

The APVMA is running a pilot to see whether moving the function of conducting or commissioning a data assessment from the APVMA to the private sector:

- is feasible
- can introduce efficiencies for industry, while
- maintaining the APVMA's ability to make quality decisions for registration and variation applications.

The pilot aims to identify and rectify any potential issues and demonstrate whether the proposed process can increase the efficiency of application processing.

Only the efficacy and target crop/animal safety assessment will be considered in this pilot. The efficacy and target crop/animal safety assessment is considered less complicated because it does not require standard setting or the publication of outcomes.

A list of efficacy reviewers selected to participate in the pilot and their areas of expertise is available on the APVMA website. Participating applicants can select a reviewer from this list to assess the efficacy and target crop/animal safety data submitted for applications involved in the pilot.

If the pilot demonstrates that the above objectives can be met, the APVMA aims to modify processes to allow for contestability of efficacy and target crop/animal safety for all applications and may investigate whether it is feasible to expand contestability to other data assessment areas.

Figure 1: Outline of the pilot process

2 PROPOSAL

2.1 Timeframes and fees

While the efficacy and target animal safety data will be assessed prior to submission of an application, the APVMA will require time to consider the assessment report and the data provided. If the assessment report provided does not meet the quality and accuracy expectations of the APVMA the report may be set aside and a new report commissioned by the APVMA. For this reason the appropriate part 8 module level timeframe and fee will be added to all pilot applications. If the APVMA is satisfied with the quality of the assessment report provided the module 8 fee will be refunded. If the APVMA is not satisfied with the quality of the assessment report provided the module 8 fee will be retained and used to pay for a second assessment of the data provided. The APVMA can be satisfied of the quality of the assessment report but still not agree with the recommendations made.

2.2 Reviewers

A list of reviewers is available on the APVMA website (‘the list’). The entry for each reviewer on the list includes the products or types of data they are able to assess for the pilot. Applicants participating in the pilot must select an appropriate reviewer from the list to assess their efficacy and target crop/animal safety data. Assessment reports provided that are not from a reviewer on the list or are not a product type listed for that reviewer will not be accepted as part of the pilot. As is the current process, reviewers are required to declare that they have no conflict of interest with respect to the proposed product or the data supporting registration of the proposed product using the APVMA conflict of interest declaration form. Reviewers are also required to complete a data list, provided by the applicant, identifying all of the data provided to them for assessment and which data items they relied on the make their recommendations.

All reviewers joining the list are advised of and agree to the APVMA’s expectations regarding report format, content and quality. Reviewers providing two assessment reports that do not meet the APVMA expectations will no longer be eligible to participate in the pilot and will be removed from the list. The list, the APVMA’s expectations of the reviewers on the list, the conflict of interest declaration form and the data list template are available on the APVMA’s website.

The APVMA is responsible for compilation and maintenance of the list but will have no involvement in interactions between applicants and the reviewers on the list. The APVMA makes no guarantees relating to the work provided to an applicant by a list reviewer. Each list reviewer will be able to set his or her own fees and negotiate his or her own timeframe with each applicant.

2.3 Identification of specific applications

Participation of agvet companies (‘applicants’) in the pilot will be on a voluntary basis. Pilot applicants should be open to the idea of contestability, must be able to nominate a suitable product for inclusion in the pilot and must understand the pilot process and how the outcome may impact their application and decision timeframes.

Participants should be aware that even if they provide an assessment report supporting all of their proposed claims, the APVMA’s decision may be to allow only some of the claims or may be that the APVMA cannot be

satisfied of the efficacy or safety criteria. The participating applicants must understand that the APVMA delegate will be making decisions based on the s14 criteria.

Participating applicants must include with their pilot application the name of the reviewer who performed the data assessment report submitted, all of the data and argument provided to the list reviewer, the data list completed, signed and dated by the reviewer and the conflict of interest declaration completed, signed and dated by the reviewer. Data or argument not considered by the reviewer must not be included in a pilot application.

Pilot applications can be for registration of a new product or for variation of a registered product but must require assessment of efficacy and/or target crop/animal safety data. Pilot applications may also include assessment of other risk areas (chemistry, residues, trade, toxicology, work health and safety or environment). These other risk areas will be assessed according to the current APVMA application processes. Where other risk areas are being assessed in a pilot application for a product including a new active constituent, the applicant may choose to submit a 'timeshift' application (phased submission), where all other data are submitted with the application and an agreement is made for when the efficacy and target crop/animal safety data and assessment report will be provided.

2.4 Design

Please note that this is the design for the pilot project. The pilot is a 'proof of concept' tool. If the pilot demonstrates that contestability of the efficacy assessment offers advantages to the APVMA and the applicant, further consultation will be conducted regarding how the data assessment process may look in the future.

The pilot applications will be submitted under the appropriate application item number for the type of application and may include assessments other than efficacy and target crop/animal safety.

The applicant will have their efficacy and target crop/animal safety data assessed by their chosen list reviewer prior to submitting the application to the APVMA. The assessment report prepared by the list reviewer and the efficacy and target crop/animal safety data will both be submitted with the application. The appropriate part 8 module level will be assigned and the full part 8 module fee must be paid. If the APVMA determines that the assessment report provided is not of an acceptable quality or does not accurately represent the data provided, the APVMA may have the data assessed again, either internally or by an APVMA-appointed efficacy reviewer. The applicant will be notified if this is the case.

If the APVMA is satisfied with the quality of the report provided the part 8 module fee will be refunded in full.

The APVMA will consider the assessment report and may:

- agree with the assessment report provided
- not agree with the assessment report provided and refuse the application
- not agree with the assessment report provided and grant the application with amendments (if the application is for registration of a new product) or
- set aside the assessment report and complete a second assessment of the efficacy and target crop/animal safety data if there is an issue with the quality of assessment report provided.

In all instances, the APVMA will make the final decision on the satisfaction of the efficacy and safety criteria.

When the pilot application is finalised, or if there are other risk areas being assessed when the efficacy assessment is finalised, the applicant will be asked to complete a survey about their experience and whether they feel such a change in process would reduce their regulatory burden or make the APVMA application process more efficient. The list reviewer and APVMA staff members involved in the pilot processes will complete similar surveys.

2.5 Reporting

Data generated during the pilot will be analysed to form the basis of a report. The report will consider aspects such as the proportion of pilot applications requiring re-assessment of data, details of these applications (including application item, module level and product type) and the perceptions of participating applicants and APVMA staff involved in the pilot processes. The report will include any problems identified and rectified during the pilot, any issues identified that may impact on future processes involving contestability, recommendations regarding the continuation or expansion of contestability and recommendations for future processes if contestability of data assessments is to be adopted. The completed report will be published on the APVMA website.

3 PROCESS DETAIL

3.1 Detail of proposed process

A pilot reviewer list is available on the APVMA website. Details of the product types each reviewer can assess for the pilot are included with the list. The APVMA's expectations of list reviewers is also available on the APVMA website.

Agvet companies/consultants can nominate appropriate applications for inclusion in the pilot by contacting the APVMA's efficacy assessment coordinator (email: APVMA.efficacy@apvma.gov.au). A letter outlining the APVMA's expectations of pilot applicants and what pilot applicants can expect from the APVMA will be provided to those who nominate an application. This information is also available on the APVMA's website.

Each pilot applicant will arrange for their efficacy and target crop/animal safety data to be assessed by an appropriate reviewer from the list. Only assessment reports completed by reviewers on the list who have the appropriate expertise listed will be accepted for the pilot. The arrangement between the reviewer and the applicant is a commercial one and does not involve the APVMA. The applicant should ensure the chosen reviewer completes, signs and dates the APVMA conflict of interest declaration form which is available on the APVMA website.

The reviewer will provide the applicant with an efficacy and target crop/animal safety assessment report. The report must be signed and dated and must include a completed data list. The data list (provided by the applicant—template available on the APVMA website) must include all data items the reviewer was provided and identify all the data items the reviewer relied on to make their recommendations.

The applicant will submit their application under the appropriate item for the application type. The pilot application must include:

- the completed application form identifying the application as part of the pilot
- selection of the appropriate part 8 module level for the application
- all of the data and argument provided to the reviewer (it must not contain any additional data or argument not provided to the reviewer)
- the name of the reviewer who assessed the data and provided the data assessment report you are submitting with the pilot application
- the conflict of interest declaration form, completed, signed and dated by the reviewer whose report you are submitting
- the data list completed, signed and dated by the reviewer whose report you are submitting, and
- the signed and dated data assessment report provided by the reviewer.

The pilot application will include the appropriate modules for the application and the full module fees will be paid.

The APVMA will refund the part 8 module fee when the assessment report provided has been determined to be of acceptable quality. If the assessment report is not determined to be of acceptable quality the report will be set aside, the entire part 8 module fee will be retained and the APVMA will commission a second review of the data. The APVMA will make a determination as to the quality of the assessment report provided in a timely manner so

that if a second assessment is required it will fall within the timeframe allowed for the appropriate part 8 module level.

The application will be managed following the usual application processes.

The risk manager will complete the application by making recommendations to the delegate (this may include assessments of other risk areas).

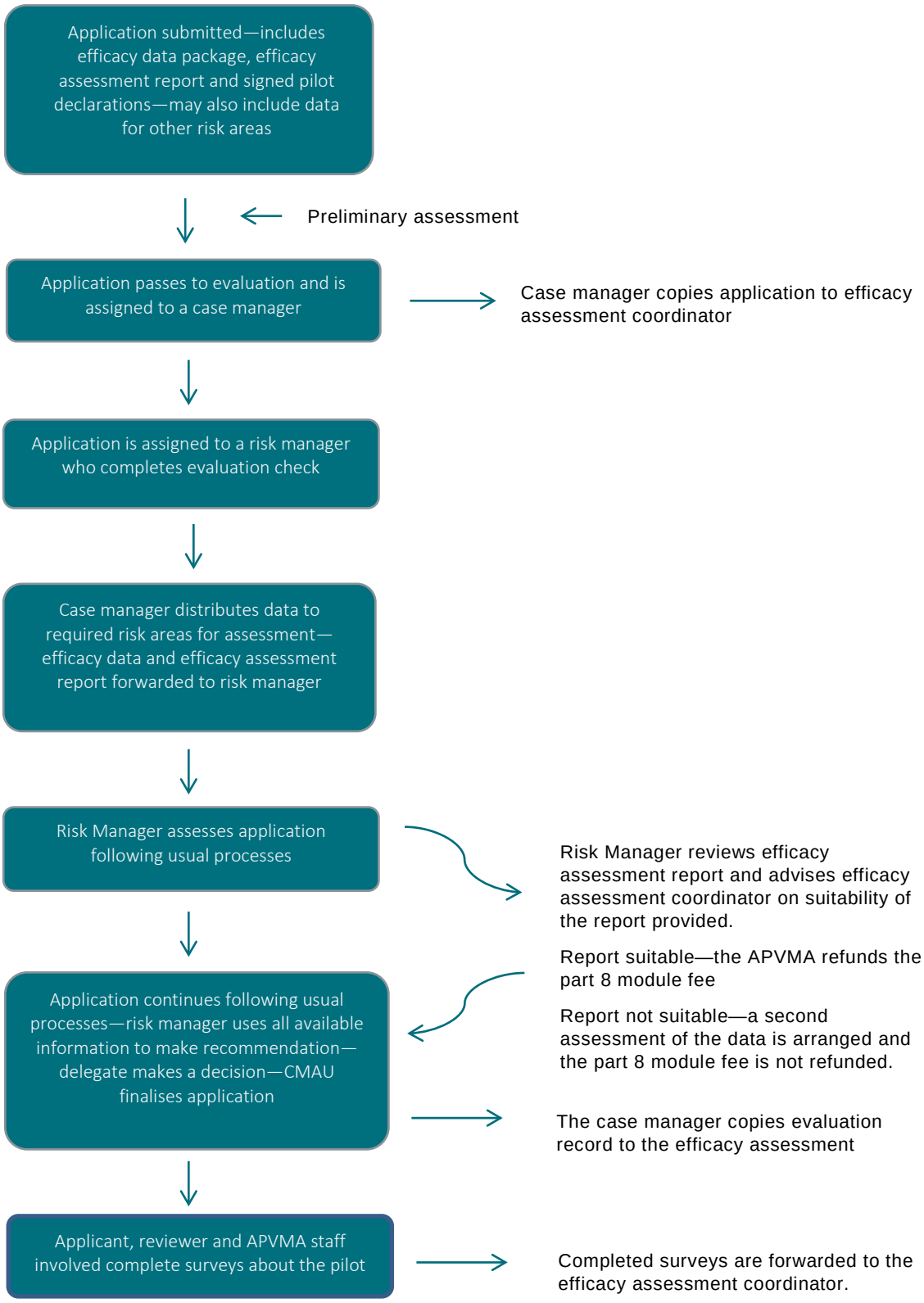
The delegate will make the decision on whether to grant the application following the usual application process.

The APVMA will finalise the application following the usual application process.

Following completion of the pilot application (or if the application includes assessments of other risk areas, following completion of the efficacy assessment) the applicant will be asked to complete a survey. The survey will include questions about their experience with the pilot and their views on whether the proposed process would reduce their regulatory burden or increase the efficiency of the APVMA. The reviewer and the APVMA staff involved in the pilot application will be asked to complete similar surveys on their experience with the pilot, whether they had any concerns about the efficacy assessment report provided, how the problems were resolved and their views on whether the proposed process will reduce regulatory burdens or increase the efficiency of the APVMA.

This pilot process will be managed by the APVMA's efficacy assessment coordinator.

Figure 2: Flowchart for an application submitted for the pilot



APPENDICES

ABBREVIATIONS

APVMA	Australian Pesticides and Veterinary Medicines Authority
s14	Section 14 of the Agricultural and Veterinary Chemicals Code Act 1994
WHS	Worker Health and Safety
Agvet	Agricultural and Veterinary Chemical
CMAU	Case Management and Administration Unit