Contestability of the efficacy assessment

Proposal for a pilot to determine the effectiveness of applicants providing completed efficacy assessments with submission of registration or variation applications.
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# ABBREVIATIONS

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- Figure 1: Outline of the pilot process
- Figure 2: Flowchart for an application submitted for the pilot
1 INTRODUCTION

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’s 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 such a vast range of application types that the APVMA assesses.

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 administration processes within the APVMA,
- increase the efficiency of application processing, and
- open the area of data assessment to competition.

1.4 How are we doing it?

The APVMA proposes to run 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 increase the efficiencies for industry, while
- maintaining the APVMA’s ability to make quality decisions for registration and variation applications.
The pilot will aim 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 publication of outcomes.

A list of efficacy reviewers selected to participate in the pilot and their areas of expertise will be published 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.

Expressions of interest will be sought from applicants that have suitable applications and are willing to participate in the efficacy contestability 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

- **APVMA provides a List of expert reviewers**
- **Applicants select reviewers from list to conduct reviews of efficacy & target crop/animal safety data**
- **Applicants submit the efficacy & target crop/animal safety data assessment reports and the data with their product application**
- **Both Applicants & APVMA staff answer questions about the Pilot process**
- **APVMA makes decisions as to whether the efficacy and safety criteria have been met – applications finalised**
- **APVMA considers the data assessment reports & data provided as per the current process**
- **Pilot data collated, analysed and reported**
- **Recommendations made regarding continuation or expansion of contestability**
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 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 assessment report provided the module 8 fee will be refunded. If the APVMA is not satisfied with the assessment report provided the module 8 fee will be retained and used to pay for a second assessment of the data provided.

2.2 Reviewers

A list of reviewers will be published from which applicants can select a reviewer to assess their efficacy and target crop/animal safety data (‘the List’). The reviewers must have the appropriate knowledge and skills to adequately assess the efficacy and target crop/animal safety data for the various product types. As is the current process, reviewers will be 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.

All reviewers joining the List will be advised of and agree to the APVMA’s expectations regarding report format, content and quality. Reviewers that provide 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 and the consequences of not meeting those expectations will be published on the APVMA’s website.

The APVMA will be 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 declare that the data provided to the APVMA with the application is identical to that provided to the reviewer to conduct the review.
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, WHS 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, 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 proposed 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 & 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 or 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
- complete a second assessment of the efficacy and target crop/animal safety data if there is an issue with the assessment report provided.

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

When the pilot application 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 APVMA staff members involved in the pilot processes will complete a similar survey.
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 a 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.
3 PROCESS DETAIL

3.1 Detail of proposed process

- The APVMA publishes the pilot reviewer List on the APVMA website. Details of the APVMA’s expectations of the individuals on the List and the consequences of not meeting those expectations will be published.

- Agvet companies/consultants will be invited to participate in the pilot. Details of the pilot design, the APVMA’s expectations and what they can expect from the APVMA will be provided to the Agvet companies/consultants.

- Agvet companies/consultants who agree to participate will nominate specific applications for inclusion in the pilot (either new registrations or efficacy variations to registered products).

- Each applicant will arrange for their efficacy and target crop/animal safety data to be assessed by an appropriate reviewer from the List.

- The reviewer will provide the applicant with an efficacy and target crop/animal safety assessment report.

- The applicant will submit their application under the appropriate item for the application type. Both the efficacy and target crop/animal safety assessment report and the data will be included with the pilot application. The applicant will be asked to declare that exactly the same data package was provided both to the APVMA and to the reviewer to prepare the included efficacy assessment report. The applicant will be asked to declare which expert completed the efficacy assessment report provided. The application will be identified as a pilot application.

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

- The APVMA will refund the module 8 fee when the assessment report provided has been determined as acceptable.

- 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 areas).

- The Delegate will determine the application following the usual application process.

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

- Following completion of their application the applicant will be asked to complete a survey on 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 APVMA staff involved in the pilot processes will be asked to complete a survey 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 process will be managed by the Efficacy Assessment Coordinator.
Figure 2: Flowchart for an application submitted for the pilot

Application submitted - includes efficacy data package, efficacy assessment report and signed pilot declarations – may also include data for other risk areas.

Preliminary Assessment

Application passes to evaluation & is assigned to a Case Manager

Case Manager copies application to Efficacy Assessment Coordinator

Application is assigned to a Risk Manager who completes Evaluation Check

Risk Manager assesses application following usual processes

Risk Manager reviews efficacy assessment report and advises on suitability of the report provided.
Report suitable – the APVMA refunds the part 8 module fee
Report not suitable - a second assessment of the data is arranged & the part 8 module fee is not refunded.

Application continues following usual processes – Risk Manager uses all available information to make recommendation - Delegate makes a decision – CMAU finalises application

The Case Manager copies Evaluation Record to the Efficacy Assessment Coordinator.

Risk Manager and applicant complete surveys about the pilot process

Completed surveys are forwarded to the Efficacy Assessment Coordinator.
# ABBREVIATIONS

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