



**Australian Government**  
**Australian Pesticides and  
Veterinary Medicines Authority**



# MANUAL FOR EXTERNAL SCIENTIFIC REVIEWERS

Version 3

JULY 2011

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## GENERAL INFORMATION

### 1.1 Introduction

The APVMA evaluates applications for product registration for pesticides and veterinary medicines under the criteria of human safety, environmental safety, trade and efficacy. The APVMA also conducts chemical reviews on currently registered pesticides and veterinary medicines if potential safety and performance risks have been identified.

Some of these assessments or reviews are outsourced to external scientific reviewers (or external reviewers). The APVMA relies on these external reviewers to provide it with a scientific assessment of the data, review component report, existing review component / registration report, and to make informed recommendations regarding those assessments.

This manual is designed to assist external reviewers in providing such assessments and recommendations.

This manual applies to external reviewers who are acting as a private individual or are employed by an organisation other than the APVMA.

### 1.2 The legislative basis for APVMA decisions regarding registration or review

The APVMA must comply with its governing legislation (primarily the Agvet Code, see [http://www.apvma.gov.au/about\\_us/AgrVetChemCode94.rtf](http://www.apvma.gov.au/about_us/AgrVetChemCode94.rtf)) when it makes a decision in order to grant an application for product registration section 14 of the Agvet Code is utilised. The same criteria apply to applications for variation of registration (section 29 of the Agvet Code).

To review currently approved chemicals and registered products the APVMA may utilise sections 32, 33, 34, 34(A) and 43(3) of the Agvet Code when making its decision.

These powers allow the APVMA to reconsider the registration of chemical products, the approvals of active constituents and labels, and to require relevant information to be provided by sponsor companies. Relevant trial work can be requested by the APVMA to generate results needed for the review, and additional information can be requested for delivery within specific timeframes.

Outcomes of a review can include label modification (e.g. modification or removal of some uses, changes or additions to warnings, use instructions and FAISD) the suspension or cancellation of the approval of an active constituent, the registration of a product, or the approval of a product's label.

### 1.3 Identity of reviewers

In the past the APVMA has been able to protect the identity of external reviewers. However, because of the Agvet Code's data protection provisions (refer to Regulation 22 (b) of the Agvet Code), Freedom of Information (FOI) requests and recent Administrative Appeals Tribunal (AAT) decisions, there are some issues with confidentiality which must be highlighted.

### Registration assessment report

When the APVMA has received a final assessment report, including an executive summary from an external reviewer, the executive summary is published on the APVMA website if the application is granted. If an external reviewer provided the registration assessment report, the phrase 'external reviewer' will be published. Note that the reviewer's name will not be published.

### Review component report

When the APVMA has received a review component report, including an executive summary, this document will be included in the final APVMA Review Findings Report. If an external reviewer provided a review component report, the phrase 'external reviewer' will be published. Note that the external reviewer's name will not be published.

### Peer review of existing review component / registration report

When the APVMA has received a peer review of a review component or registration assessment report, the organisation producing the original review component or registration assessment report will receive a copy. The name of the 'external reviewer' providing the peer review report will not be released.

However, if someone lodges an FOI request with the APVMA pertaining to a review component or registration assessment report, there is legal precedent (in an AAT case) that the name of the individual external reviewer **may** be disclosed. Note that the name will not be released without the knowledge of the person involved, who will be given the opportunity to comment and make a case for non-disclosure, prior to the release of any information.

## APVMA Contact details:

**Review:** Danielle Cregan  
02 6210 4749  
[danielle.cregan@apvma.gov.au](mailto:danielle.cregan@apvma.gov.au)

**Pesticides:** Dino Martiniello  
02 6210 4748  
[dino.martiniello@apvma.gov.au](mailto:dino.martiniello@apvma.gov.au)

**Veterinary Medicines:** Thea Reiman  
02 6210 4726  
[thea.reiman@apvma.gov.au](mailto:thea.reiman@apvma.gov.au)

**Director, Scientific Services:** Sue Wurcker  
02 6210 4809  
[susan.wurcker@apvma.gov.au](mailto:susan.wurcker@apvma.gov.au)

## 1.4 Confidentiality

External reviewers should be aware that registration applications, review component reports and registration / review peer review reports are confidential and may contain commercially sensitive material. This means that the information pertaining to these reports being considered by the APVMA is to be treated as Confidential Commercial Information (CCI), unless it has been published by the APVMA in an application

summary or review component report on the APVMA website (see [http://www.apvma.gov.au/data\\_protection/appl\\_summaries.shtml](http://www.apvma.gov.au/data_protection/appl_summaries.shtml)).

External reviewers must declare that they are aware of the CCI provisions at section 162 of the Agvet Code (refer [http://www.apvma.gov.au/about us/AgrVetChemCode94.rft](http://www.apvma.gov.au/about_us/AgrVetChemCode94.rft)). An external reviewer declaration (refer Attachment B – External reviewer scientific declaration) is attached to the work order refer (Attachment A – APVMA work order) for this purpose. The external reviewer must sign this and return it to the APVMA prior to commencing the assessment.

From the external reviewer's perspective the following should generally be considered CCI unless published in a registration application summary:

- active constituent / product name/s
- application details
- formulation details
- number and types of studies that accompanied the application
- applicant / registrant details
- manufacturing sites
- manufacturing process

From the external reviewer's perspective the following should generally be considered CCI unless published in a review component report:

- registration details
- formulation details
- manufacturing sites
- manufacturing process
- details of people providing comment on a review

Because of the requirement to publish registration application summaries (see [http://www.apvma.gov.au/data\\_protection/appl\\_summaries.shtml](http://www.apvma.gov.au/data_protection/appl_summaries.shtml)), the existence of the majority of registration applications being considered by the APVMA is no longer CCI. Nevertheless, if an external reviewer is asked about an application / review component report, they should reply in terms of: 'I am unable to discuss the details of any application for any product / review that might be with the APVMA'.

The application should be discussed only with persons who may be able to assist with the assessment under the same strict conditions of confidentiality. Under no circumstances should it be discussed with outside parties such as competitor chemical companies, primary producer groups or the media. Registration applications, existing review component reports and external reviewer's notes (including electronic records) must be kept in a secure manner (refer Section 2 – Safe Handling of APVMA C-I-C information).

### **APVMA COMMERCIAL-IN-CONFIDENCE INFORMATION**

Earlier in Section 1.4 reference has been made to CCI, which is defined in the Agvet Code and is specific to the APVMA. However, CCI is not the same as Commercial-in-Confidence (C-I-C) information, which has a broader definition in the wider community. C-I-C information refers to facts or knowledge that are not in the public domain and if that information were released would:

- Cause financial loss or loss of earning potential to, or facilitate improper gain or advance for, individuals or private entities; or
- Disadvantage the Government in commercial or policy negotiations with others; or
- Breach proper undertakings to maintain the confidentiality of information provided by third parties; or
- Breach statutory restrictions on the management and disclosure of information.

If an external reviewer is unsure whether certain information may be considered APVMA Commercial-in-Confidence (C-I-C) information, they should contact the nominated project officer that is indicated in Item 7 of the Schedule in the Deed of Standing Offer.

## 1.5 Conflict of interest

External reviewers must declare to the APVMA any potential conflict of interest between the material being assessed and any other assessment or research work that they have carried out in the past, are currently working on or have made a commitment to work on in the future that could impact on an objective assessment of the material. **Highlighting a possible conflict of interest may not disqualify an external reviewer from continuing the assessment.** However, that determination must be made by the APVMA.

When the APVMA project officer asks an external reviewer to conduct an assessment it is essential the external reviewer considers a variety of questions to ascertain whether there could be a potential conflict of interest prior to commencing the assessment, including whether:

- I have been involved in trials or other research and development sponsored by the Registrant/Applicant
- I have been involved in trials / research and development in relation to the product being reviewed
- I hold shares in, or have other personal financial involvement in, the Registrant/Applicant
- I have been involved in trials or other research and development work with another Registrant/Applicant who has a chemical product that is in direct competition with the Chemical Product
- I am aware of a conflict of interest with respect to the material being reviewed and/or any other review or research work that could adversely impact on my objective review of the material

The above list is not exhaustive, but is a guide to alert the external reviewer to what types of conflicts may occur.

### Prior to the data assessment

If an external reviewer answers 'yes' to any of the above questions, or has any other concerns relating to a potential conflict of interest, the external reviewer should contact the nominated project officer or the Manager, Scientific Assessment Services, immediately to discuss the situation.

The APVMA will determine either that:

- the conflict of interest is negligible and the external reviewer may still conduct the assessment
- OR
- there is a conflict of interest that would necessitate the external reviewer ceasing work on the assessment and another external reviewer being appointed.

The APVMA will make a decision relating to the potential conflict of interest and either the nominated project officer or the Manager, Scientific Assessment Services, will contact the external reviewer with the decision.

Depending on the decision either the current external reviewer may commence the assessment or another external reviewer will be sought.

Attached to the work order is a Reviewer's Declaration form, all external reviewers must complete, sign and return the Reviewer's Declaration within 5 days of receipt and prior to commencement of the data assessment.

### **During the assessment period**

If at any time during the assessment period the external reviewer realises that there may be a potential conflict of interest (as stated in the External Scientific Reviewer's Declaration), the nominated APVMA project officer or the Manager, Scientific Assessment Services, must immediately be contacted. In these cases, the APVMA will determine whether:

- the conflict of interest is negligible and the external reviewer may continue the assessment
- or
- there is a conflict of interest that would necessitate the external reviewer ceasing work on the assessment and another external reviewer being appointed.

## **1.6 Insurance for external reviewers**

External reviewers are only required to obtain insurance if the APVMA requests them to do so. If the APVMA does not request insurance, the external reviewer is not obliged to obtain insurance.

## **1.7 Quality performance standards**

The APVMA requires that an external reviewer will:

ensure that a signed external scientific reviewer declaration has been sent to the APVMA prior to commencing an assessment;

be aware of and meet timeframes as specified in the work order;

be aware of and meet the quality criteria that is included in the work order;

ensure their assessment is appropriate for regulatory purposes;

present the registration assessment report or review component report or registration / review component report in an appropriate format and ensure that these documents have direct relevance to the proposed product registration and / or label approval and / or APVMA Review Findings Report; and

clearly highlight any major issues of concern in the covering letter.

## **1.8 Disposal of APVMA Commercial-in-Confidence Information**

APVMA Commercial-in-Confidence (C-I-C) information, this may include data, studies, research or trial work that the APVMA has sent to an external reviewer may be disposed of in two different methods. The external reviewer must either:

return all APVMA C-I-C information to the APVMA; or

arrange for secure destruction of all APVMA C-I-C information.

Do not put APVMA C-I-C information into a normal garbage disposal service, unless it has been shredded. If you are using a shredder to securely dispose of APVMA C-I-C information use only a B Class crosscut shredder, which reduces waste to a particle size of 2.3mm x 25mm or less.

If unsure of the most appropriate and cost-effective method for destruction of APVMA C-I-C information please contact the nominated project officer at the completion of the assessment. For further information on secure disposal of APVMA C-I-C information refer to sub-section 2.3 – Information handling, storage and disposal.

## SAFE HANDLING OF APVMA COMMERCIAL-IN-CONFIDENCE INFORMATION

On the 1<sup>st</sup> July 2007 the APVMA became part of the Australian Government. Due to this move the APVMA has additional responsibilities for how we collect and receive C-I-C information to fulfil our functions. The APVMA expects all external reviewers who access or hold this C-I-C information to protect it.

The term 'information' within this context refers to any form of information, including:

Documents and papers;

Data;

Software or systems and networks on which the information is stored, processed or communicated;

Intellectual information (knowledge) acquired by individuals; and

Physical items from which information regarding design, components or use could be derived.

These additional responsibilities are outlined in six principal documents that govern the general protection and disclosure of official government information, they are:

Criminal Code Act 1995 (the Criminal Code);

Crimes Act 1914 (the Crimes Act);

FOI Act;

Privacy Act 1988 (the Privacy Act)

Archives Act 1983 (the Archives Act);

Protective Security Manual (PSM); and

Australian Government Information and Communications Technology Security Manual (ISM) ACSI 33.

External reviewers that are dealing with APVMA C-I-C information should ensure they observe the following minimal procedural requirements - security (use and storage), transmission and disposal of that information. External reviewers must be prepared to accept responsibility for the safe custody of C-I-C information provided to them by the APVMA. Part of this responsibility includes adhering to the following guidelines.

### 2.1 Information access

For external reviewers it is important that APVMA C-I-C information is not made available to an individual that is not listed as specified personnel in the Deed of Standing Offer, Item 5 of the Schedule.

If an individual who is not listed as specified personnel in the Deed of Standing Offer, Item 5 of the Schedule does have access to APVMA C-I-C information it must only be for the efficient conduct of the business at hand.

It is important that external reviewers do not discuss APVMA C-I-C information with unauthorised persons, within earshot of unauthorised persons, this includes while on the telephone to other authorised persons or the APVMA

The external reviewer working from home should recognise and accept that his or her immediate family, other family members and friends do not do not have a 'need-to-know' in relation to APVMA C-I-C information. 'Need-to-know' is the principle that the availability of APVMA C-I-C or official information should be limited to those who need to use or access the information to do their work. External reviewers should ensure that family and friends do not have access to paper based or electronic APVMA C-I-C information, either intentionally or unintentionally.

## 2.2 Information labelling

All APVMA C-I-C information, regardless of its format, must have a classification label. The documents containing APVMA C-I-C information that the external reviewer may produce:

registration assessment report;

review component report;

Peer review of existing review component / registration report; and

covering letter.

All paper-based and electronic copies of APVMA C-I-C information (refer above) must be clearly marked COMMERCIAL-IN-CONFIDENCE at the top and bottom of each page. Documents with covers, should show the protective marking on the front cover, title page and rear cover. Any binding or fastening of pages must not obscure the protective marking. If a page is to be folded, the classification marking must remain visible after folding.

The classification marking must be in capitals, in bold text and of a minimum height of 5mm, preferably red.

If a summary or covering letter does not contain APVMA C-I-C information, the summary may remain unclassified and marked UNCLASSIFIED or not be marked at all. It must indicate that it covers a document of a higher classification.

Information such as journal articles are considered to be in the public domain and therefore do not require special treatment.

Equipment or components, including removable electronic and optical media, such as magnetic tapes, CD-ROMs, microfilms, photographs, removable disks, etc, with APVMA C-I-C information stored on them, must be marked clearly COMMERCIAL-IN-CONFIDENCE. Please note that PEDS are not included.

If these items have ever been used to process information classified at a level higher than COMMERCIAL-IN-CONFIDENCE this is the level that should be marked on the piece of equipment.

External reviewers should ensure that all APVMA C-I-C information stored within a database or network is associated with an appropriate classification marking if the information could be exported to a different system, database or network.

## 2.3 Information handling, storage and disposal

The external reviewer must not copy or reproduce in any form APVMA C-I-C information. If extra copies of the document are required, additional copies must be requested from the APVMA.

APVMA C-I-C information must not be extracted from documents that have a classification of APVMA C-I-C information supplied to external reviewers, without the written approval of the APVMA, unless it is to be used in written correspondence to the APVMA.

When APVMA C-I-C information is not in use, it must be stored in a lockable filing cabinet. The keys to the filing cabinet must be secured.

Within six months of the payment of an assessment report external reviewers are expected to correctly follow Section 1.8 Disposal of APVMA C-I-C information outlined in this manual.

## 2.4 Protecting Computers

Computers have intrinsic value and therefore are at risk from theft. This results in both the loss of the equipment and any APVMA C-I-C information that has been stored on the computer. Computers, including laptops, must be given the same level of protection as similarly classified paper-based information.

Where an external reviewer works from home and people other than the external reviewer access a computer or laptop there is also an increased risk that viruses could be introduced to the machine or information in the computer could be corrupted or deleted.

It is recommended that external reviewers reduce potential vulnerabilities in their systems and ensure all computers or laptops used for work carried out for the APVMA have the following in place:

Computers and / or laptops are password protected

Passwords are safeguard and not shared unnecessarily

Remove unnecessary file shares

Only store APVMA C-I-C information on a data stick rather than on the hard drive of your computer or laptop. If the hard drive is used, partition the hard drive so that APVMA C-I-C information can be quarantined and that the partition is password protected. Delete the classified files from systems when work for the APVMA is completed, defrag hard drives and reformat data sticks

Disable access to all unnecessary input/output functionality

Wireless Technology:

The current APVMA policy regarding the use of wireless technology is that it is too vulnerable and should not be used under any circumstances.

Utilise active content blocking by using:

Filters to block unwanted content and as a defence against applications that cannot be patched;

Ensure patching is up to date

Use settings within applications to disable unwanted functionality

Use digital signatures to restrict active content to trusted sources only

Anti-virus scanners:

Have anti-virus software installed on all computers or laptops

System users do not have the ability to disable the scanner

Check vendor virus pattern signatures for updates daily or the first time you log in after an absence from using for your computer or laptop

Apply virus pattern signature updates as soon as possible after vendors make them available

Regularly scan all disks and data sticks prior to use

Log off the computer or laptop at the conclusion of the work period

Maintenance and repairs of hardware:

If possible use an appropriately cleared and briefed technician for the maintenance and repairs of hardware products containing APVMA C-I-C information on-site

If an uncleared technician is used on-site to undertake maintenance or repairs of a hardware product, an authorised person who takes due care and all responsible measures to ensure the integrity of the product must escort the technician at all times to ensure that APVMA C-I-C information is not disclosed

It is advised that off-site repairs be avoided. If off-site maintenance is required, remove all APVMA C-I-C information and make sure the computer or laptop is sanitised before permitting the hardware off-site.

It is recommended that external reviewers who use laptops use [soft labelling](#) where possible to reduce their attractiveness value.

It is recommended that external reviewers affix an additional label to the laptop asking finders to hand the equipment in to any Australian police station.

When they are not in use laptops must be stored in a lockable filing cabinet. The keys to the filing cabinet should be secured.

For the protection of computers and APVMA C-I-C information it is advised that an external reviewer that works from home lock their work area when they are not working on APVMA work. The keys to the work area must be secured.

## 2.5 Portable Electronic Devices

Similar to computers Portable Electronic Devices (PEDS) have intrinsic value and therefore are at risk from theft. PEDS are particularly vulnerable to information compromise as they are portable and attractive, attackers could gain access to APVMA C-I-C information stored on these devices if they are lost or stolen or oversee information while a PED is in use or overhears a conversation while voice calls are being made in an unsecured environment.

PEDS include, but are not limited to; personal digital assistants, mobile phones and smart-phones, two-way email devices and digital audio players / recorders.

External reviewers using PEDS must NOT store any APVMA C-I-C information on them.

External reviewers using PEDS must not conduct telephone conversations discussing APVMA C-I-C information with Bluetooth functionality enabled. The current APVMA policy regarding the use of wireless technology (including Bluetooth) is that it is too vulnerable and should not be used under any circumstances.

It is recommended that external reviewers with PEDS only use approved products where possible and use the device in a physically protected area.

It is recommended that external reviewers who use PEDS use [soft labelling](#) where possible to reduce their attractiveness value.

It is recommended that external reviewers affix an additional label to the PED asking finders to hand the equipment in to any Australian police station.

The APVMA reserves the right to confiscate, examine, sanitise and/or destroy non-agency owned PEDS in the case of an APVMA C-I-C information and communications technology security incident.

The external reviewer must inform the APVMA of any incidents or changes in the home environment that could adversely impact on the security arrangements at the home. Such as:

Changes in the physical security of the residence

Any incident affecting the security of the residence, whether apparently related to home based work or not, such as a break-in, renovations, etc.

## 2.6 Sending APVMA C-I-C information

When the final assessment report is finalised the external reviewer is required to send a paper based and electronic copy to the APVMA. It is important when sending paper based APVMA C-I-C information that it is securely wrapped.

When sending APVMA C-I-C information by envelope the information should be double enveloped, this is achieved by using two new opaque envelopes, an inner envelope and an outer envelope. Both inner and outer envelopes must always be sealed. The outer envelope must not indicate that there is APVMA C-I-C information in the inner envelope.

If the APVMA C-I-C information being sent is too large for an envelope put it in a box or other suitable container that does not indicate that APVMA C-I-C information is in the box. The box must be securely closed so that it does not open in transit.

If the APVMA C-I-C information is delivered by hand between the external reviewer and a known APVMA staff member, the envelope should be addressed to that person as well as being double enveloped. Acceptable delivery methods are registered post or by SCEC-endorsed overnight courier – includes Star Track Express, Australia Post Courier service, Toll.

## 2.7 Transmitting APVMA C-I-C information

Faxing

External reviewers faxing APVMA C-I-C information to the APVMA must arrange for the receiver to collect the information from the APVMA's fax machine as soon as possible after it is received. Preferably by notifying the staff member by email or phone that an item has been faxed and request that they notify the sender if the fax does not arrive within an agreed period of time.

## Emailing

It is not possible for the APVMA to send or receive emails containing C-I-C information from anyone not on connected to Fed Link. The APVMA is in the process of testing a secure e-mail system called Sigaba. This secure email system will permit name@apvma.gov.au emails to send APVMA C-I-C information to people registered on the Sigaba system. This secure system should include applicants, manufacturers, external reviewers etc.

When the secure system is installed, APVMA staff will be able to send an email containing APVMA C-I-C information to specifically nominated people, with e-mails systems outside of Fed Link, instructing them they can receive APVMA C-I-C information via a secure website after they register on the website. Only people who receive this initial email will be permitted to use the secure system.

As external reviewers do not have a name@apvma.gov.au email address they cannot instigate the registration email. Which means that when Sigaba is implemented external reviewers will only be able to send emails containing APVMA C-I-C information to the APVMA.

External reviewers MUST NOT send or receive emails from the APVMA using a web based public email service.

External reviewers who are able to send the APVMA emails should ensure that all emails are given a protective marking to indicate the maximum classification of the information contained in the email, so that the recipient knows how to appropriately handle the email as a whole. Applying protective markings to an unclassified email avoids uncertainty by the recipient in forwarding the email to persons with a valid need-to-know.

External reviewers should be aware that the automatic forwarding of an email to other persons could result in the recipient seeing information for which they do not have a need-to-know or the intended recipient and/or sender considered private.

## 2.8 General information

At the close of business each day, external reviewers should take precautions to ensure that paper based and electronic APVMA C-I-C information and other official information supplied by the APVMA is protected from unauthorised access. It is suggested that a work area lock-up procedure be followed, it should include:

Log off from all systems and, if required, switch the computer or laptop off;

Ensure that all APVMA C-I-C information is locked away and the key is secured;

Ensure that laptops and other electronic media storing APVMA C-I-C information is locked away and the key is secured;

Ensure there is no APVMA C-I-C information in waste-paper bins;

Ensure that whiteboards and other displays do not show any APVMA C-I-C information, please note that special care needs to be taken with electronic whiteboards; and

Ensure windows and doors in your work area are locked and that the key is secured.

## ATTACHMENT A: APVMA WORK ORDER

### 1. WORK ORDER DETAILS:

Name:

Contact person:

Work order period:

Service required:

Service start date:

Service agreed due date:

Fee on completion: \$

Number of hours requested:

### 2. SERVICE REQUIRED:

Description of service required:

### 3. SERVICE PROVIDER - CONFIRMATION OF WORK ORDER SPECIFICATIONS

Within 5 days of receipt of the work order, please acknowledge acceptance of the work order (including timeframe and fee) and return the completed and signed reviewer declaration to the APVMA (Fax No. 02 6210 XXXX)

I agree to the Work Order details and requirements specified in sections 1, 2, 5 and 6.

Delegate signature: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

Print name: \_\_\_\_\_

### 4. SERVICE PROVIDER TO COMPLETE ON FINALISATION OF WORK ORDER

Number of hours completed:

Fee: \$

Delegate signature: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

Print name: \_\_\_\_\_

APVMA TO COMPLETE: (Items 1, 2, 5 and 6 to be approved by Manager of Section requesting the work order)

5: DATA TRANSFER: Data sent to Agency/Alternate Service Provider				
	Scoping Report	Studies	Product/use info	Other
OCSEH				
DEWHA				
Alternate Service Provider				

6: PERFORMANCE MEASURE STANDARDS – timeframes				
	Date Data Sent	Category/ timeframe	Agreed Start Date	Agreed Date Due
OCSEH				
DEWHA				
Alternate Service Provider				

APVMA Authorisation to Engage Service Provider(s):

Manager's signature: \_\_\_\_\_ Date:     /     /

Print Manager's name: \_\_\_\_\_

7: Fee for Service (To be approved by APVMA Manager)			
Date of Receipt	Days to Complete Service	Service Charge \$	Authorisation for payment
			YES/ NO

1) The work associated with this work order complies with the following quality criteria as defined in the current Service Level Agreement or Deed of standing Offer:

Key scientific issues identified;

- Clear linkages between data, risk assessment and risk management proposals;
- Overall risk assessment based on analysis and well-reasoned scientific argument (such as discussing the validity and relevance of the information considered, including the source, the appropriateness of any experimental methodology, and relevance to the regulatory proposal);
- Risk management proposals are appropriate to the risk assessment.

The work / report must contain the following elements:

- Appropriate use of the technical report format / template (including the data list where appropriate) and summarising of the study results (such as discussing the case that the information or body of evidence makes in relation to the proposal – results, consistency of results and that the facts are proven etc.);
- Readability - good use of headings, clear style with no ambiguous or inconclusive arguments or tautologies;
- The use of correct grammar, spelling, and punctuation;
- Clearly set out table formats and pagination (where appropriate); and
- Clear and accurate referencing throughout.

The absence of personal philosophies or unpublished organisational policies by the external service provider, such as;

- rejecting data on the basis of disagreement concerning the APVMA data requirements; and
- accepting data that does not comply with the APVMA data requirements.

2) When finalising this work order I had issue/s with the following quality criteria:

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Delegate signature: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

## ATTACHMENT B: EXTERNAL SCIENTIFIC REVIEWER DECLARATION

**Review:** [Insert Chemical Name]

[Please tick the relevant boxes]

### Confidential Commercial Information

1. I am aware of the confidentiality obligations under the Agvet Codes; in particular that the matters this contract relate to are not matters I can disclose to any person outside the APVMA.

### Conflict of Interest

2. In relation to the Active Constituent (and any related Products) which is the subject of this contract, I:

	Yes	No
(a) have been involved in trials or other research and development sponsored by the Registrant/Applicant	<input type="checkbox"/>	<input type="checkbox"/>
(b) have been involved in trials / research and development in relation to the product being reviewed	<input type="checkbox"/>	<input type="checkbox"/>
(c) hold shares in, or have other personal financial involvement in, the Registrant/Applicant	<input type="checkbox"/>	<input type="checkbox"/>
(d) have been involved in trials or other research and development work with another Registrant/Applicant who has a chemical product that is in direct competition with the Chemical Product	<input type="checkbox"/>	<input type="checkbox"/>
(e) am aware of a conflict of interest with respect to the material being reviewed and/or any other review or research work that could adversely impact on my objective review of the material	<input type="checkbox"/>	<input type="checkbox"/>

I certify that in making the recommendation I have exercised my own independent judgement and professional expertise.

\_\_\_\_\_  
Print reviewer name

\_\_\_\_\_  
Sign

\_\_\_\_\_  
Date

## ATTACHMENT C: EXEMPTION FROM LIABILITY FOR DAMAGES - GUIDANCE FOR EXTERNAL REVIEWERS

The APVMA is unable to provide legal advice to external reviewers this must be obtained independently. External reviewers are covered by section 69H of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the Admin Act) (exemption from liability for damages). Any, concerns about liability and indemnity can be answered with a careful reading of section 69H of the Admin Act which is as follows:

### 69H Exemptions from liability for damages

- (1) Subject to subsection (3), no action, suit or other proceeding for damages lies against the Commonwealth, the APVMA, or any other Commonwealth authority, or a person who is or has been an officer or employee of the Commonwealth, of the APVMA or of any other Commonwealth authority, or is or has been a delegate of the APVMA, a director of the APVMA, a consultant to the APVMA, an inspector, or a mediator or arbitrator appointed by the APVMA under any of the Agvet Codes, for any loss or injury directly or indirectly suffered as a result of:
  - (a) the handling of an approved active constituent for a proposed or existing chemical product; or
  - (b) the handling of a registered chemical product, a registered listed chemical product or a reserved chemical product; or
  - (c) the handling of an active constituent for a proposed or existing chemical product, or of a chemical product, in respect of which a permit or exemption has been issued or given by the APVMA; or
  - (d) an inability to use, or to use in a particular manner, an active constituent for a proposed or existing chemical product:
    - (i) because an approval, permit or exemption permitting its use, or permitting its use in that manner, has been refused by the APVMA or such an approval, permit or exemption that was previously granted by the APVMA has been suspended or cancelled; or
    - (ii) because its use, or its use in that manner, is precluded by the conditions of an approval, permit or exemption; or
  - (e) an inability to use, or to use in a particular manner, a chemical product:
    - (i) because a registration, listed registration, permit or exemption permitting its use, or permitting its use in that manner, has been refused by the APVMA or such a registration, listed registration, permit or exemption that was previously granted by the APVMA has been suspended or cancelled; or
    - (ii) because its use, or its use in that manner, is precluded by the conditions of a registration, listed registration, permit or exemption; or
  - (f) the carrying out of a step in the manufacture of a chemical product in respect of which a licence has been issued by the APVMA; or
  - (g) an inability to carry out, or to carry out in a particular manner or at particular premises, a step in the manufacture of a chemical product:
    - (i) because a licence to carry out that step, or to carry out that step in that manner or at those premises, has been refused by the APVMA or such a licence that was previously granted by the APVMA has been suspended or cancelled; or
    - (ii) because the carrying out of that step, or the carrying out of that step in that manner or at those premises, is precluded by the conditions of a licence.

As you will notice section 69H of the Admin Act provides a very broad indemnity for external reviewers in relation to actions arising in the circumstances set out above.

## GLOSSARY

AAT	Administrative Appeals Tribunal
APVMA	Australian Pesticide and Veterinary Medicines
CCI	Confidential Commercial Information
C-I-C	Commercial-in-Confidence
FOI	Freedom of information
ISM	Australian Government Information and Communications Technology Security Manual
PED	Portable Electronic Device
PSM	Protective Security Manual

## REVISION HISTORY

Revision date	Description of revision
01/07/09	First edition
01/07/10	Second edition Updates to the manual – sections 1.3, 1.5 and Attachment A – APVMA work order.
01/07/11	Third edition Update to the manual – sections 1.3.