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General information

1.1 Introduction

The APVMA evaluates applications for approval of new pesticide active constituents and registration of pesticide and veterinary medicine products. The key focus of evaluation is on the health and safety of human beings, animals and the environment. We also conduct chemical reconsiderations of registered pesticides and veterinary medicines if potential safety and performance risks have been identified.

Some of these assessments or reviews are outsourced to external reviewers. The APVMA uses external reviewers to provide us with scientific assessments of data so we can make informed recommendations based on information in existing assessments.

This manual is designed to assist external reviewers in providing such assessments, peer reviews (including of draft assessment reports) or recommendations.

This manual applies to external reviewers who are acting as private individuals or who 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 www.apvma.gov.au/node/4131. When we make a decision in order to grant an application for product registration, we use section 14 of the Agvet Code. The same criteria to those in section 14 apply to applications for variation of registration (see section 29 of the Agvet Code).

To reconsider currently approved chemicals and registered products, we may use sections 32, 33, 34, 34(A) and 43(3) of the Agvet Code when making our decision. These powers allow us to reconsider the registration of chemical products and 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 reconsideration, and additional information can be requested for delivery within specified deadlines.

Outcomes of reconsideration can include label modification (for example, modification or removal of some uses; changes or additions to warnings, use instructions or first aid instructions and safety directions; 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 limits on the use of information provisions (refer to section 34G (3) of the Agvet Code), freedom of information requests, and recent Administrative Appeals Tribunal decisions, there are several issues with external reviewer confidentiality that must be highlighted.
Registration assessment report

When the APVMA receives a final assessment report from an external reviewer, if the application is granted the executive summary is published on the APVMA website. If an external reviewer provided the registration assessment report, the phrase ‘external reviewer’ will be published. The reviewer’s name will not be published.

Reconsideration component report

When the APVMA receives a reconsideration component report that includes an executive summary, this document is included in the final APVMA reconsideration findings report. If an external reviewer provides a reconsideration component report, the phrase ‘external reviewer’ is published. The external reviewer’s name is not published.

Peer review of existing reconsideration or registration report

When the APVMA receives a peer review of a reconsideration or registration assessment report, the organisation producing the original reconsideration component or registration assessment report receives a copy. The name of the external reviewer providing the peer review report is not released.

However, if someone lodges a freedom of information request with the APVMA pertaining to a reconsideration or registration assessment report, there is legal precedent (an Administrative Appeals Tribunal case) to suppose that the name of the individual external reviewer might 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.

1.4 Confidentiality of reports

External reviewers should be aware that registration applications, reconsideration component reports and registration or reconsideration 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 reconsideration component report on the APVMA website (see www.apvma.gov.au/node/11061).

External reviewers must declare that they are aware of the CCI provisions at section 162 of the Agvet Code (see www.comlaw.gov.au/Details/C2012C00810). The Deed of Standing Offer clearly states in Schedule 1, clause 15, that an external reviewer will notify the APVMA immediately in writing if they become aware of a potential conflict of interest.

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

- active constituent or product name(s)
- application details
- formulation details
- number and types of studies that accompanied the application
- applicant or registrant details
- manufacturing sites
- manufacturing process.
From the external reviewer’s perspective, the following should generally be considered CCI unless published in a reconsideration 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 www.apvma.gov.au/node/11061 the majority of registration applications being considered by the APVMA are no longer CCI. Nevertheless, if an external reviewer is asked about an application or reconsideration component report, their reply should be: ‘I am unable to discuss the details of any application for any product or reconsideration that might be with the APVMA’.

The application at hand should only be discussed with APVMA staff. Under no circumstances should it be discussed with outside parties such as competitor chemical companies, primary producer groups or the media. Registration applications, existing reconsideration component reports and external reviewers’ notes (including electronic records) must be kept in a secure manner (refer to section 2 in this document: ‘Safe handling of APVMA sensitive information’).

**APVMA sensitive 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 sensitive information, which has a broader definition in the wider community. Sensitive information refers to facts or knowledge that are not in the public domain and that, if released, could:

- cause financial loss or loss of earning potential to, or facilitate improper gain or advance for, individuals or private entities
- disadvantage the government in commercial or policy negotiations with others
- 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 sensitive information, they should contact the nominated project officer who is indicated in the official order.

**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 affect 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 that the external reviewer considers a variety of questions to ascertain whether there could be a potential conflict of interest prior to commencing the assessment. The external reviewer should consider not only themselves but also any close personal relationships and family members. The questions are as follows:
Has the recipient been involved in trials or other research and development sponsored by a party with an interest in any products or materials that are related to the official order?  

Has the recipient been involved in trials or other research and development in relation to products or materials that are related to the official order?  

Does the recipient hold shares in a company, or have any other personal financial involvement with a party that has an interest in any products or materials that are related to the official order?  

Is the recipient involved in trials or other research and development work with another party who has a product that is in direct competition with the products or materials that are related to the official order?  

Is the recipient aware of any other conflict of interest that could adversely impact on their ability or perceived ability to make an objective review of the material or assessment of any products or materials that are related to the official order?  

Is the recipient aware of any potential conflict of interest relating to close personal relationships or family members?  

Is the recipient aware of any other potential conflict of interest?  

**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, they should immediately contact the nominated project officer or the director, Scientific Assessment Services, to discuss the situation.

The APVMA will determine that either:

- 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 a replacement 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 director, Scientific Assessment Services, will contact the external reviewer with the decision. Depending on the decision, either the current external reviewer will commence the assessment or another external reviewer will be sought.

After receiving an official order, if the external reviewer believes there may be a potential conflict of interest, they should contact the APVMA prior to the 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, the nominated APVMA project officer or the director, Scientific Assessment Services, must immediately be informed. 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 to cease work on the assessment and another external reviewer be appointed.

**1.6 Insurance for external reviewers**

External reviewers are required to obtain:
• workers’ compensation insurance (required by law) if they employ staff
• public liability policy insurance to the value of at least $5 million in respect of each claim
• professional indemnity insurance to the value of at least $5 million in respect of each claim

Sole traders are not required to obtain workers’ compensation insurance.

1.7 Quality performance standards

External reviewers must:

• be aware of and meet timeframes as specified in the official order
• be aware of and meet the quality criteria as specified in the official order
• ensure their assessment is appropriate for regulatory purposes
• present the registration assessment report, reconsideration component report or registration or reconsideration component report in an appropriate format and ensure that these documents have direct relevance to the proposed product registration, label approval and/or APVMA reconsideration findings report
• clearly highlight any major issues of concern in a covering letter.

1.8 Disposal of APVMA sensitive Information

APVMA sensitive information, which may include data, studies, research or trial work documentation that the APVMA has sent to an external reviewer, must be returned to the APVMA. Do not put APVMA sensitive information into a normal garbage disposal service.

1.9 Security clearances

External reviewers are only required to obtain a security clearance in the form of a police check if the APVMA requests a reviewer to do so. The APVMA will request an external reviewer to undertake and provide a police check to the APVMA when the sensitivity of information we are providing to an external reviewer requires this additional security measure.

1.10 Payment of fees

The APVMA will pay for assessments after the assessment is finalised and the APVMA has received and accepted the FTR and a completed official order.

The external reviewer should send a valid tax invoice to the case management officer, who will reconcile the tax invoice against the agreed official order.

Fee Structure for Antimicrobial Resistance and Immunobiological Assessments

The APVMA will pay within 30 days of receipt of a valid tax invoice. The scale of fees is as follows:

• Level 1—$5,666 or $168 per hour if greater than 48 hours (estimate agreed between parties)
• Level 2—$2,398 or $168 per hour if greater than 21 hours (estimate agreed between parties)

If a reviewer believes that an assessment will take longer than the estimated hours stated above the reviewer is required to liaise with the APVMA PE to negotiate and confirm the number of additional hours
that can be worked and ultimately be charged to the APVMA. For example, if a reviewer has completed 75 per cent of the hours included in an assessment (Level 1 – 36 hours, Level 2 – 16 hours and Level 3 – 8 hours) and they believe they will require additional hours to complete the work they must contact the APVMA PE and gain approval for any additional hours above the total number for the level being worked on (Level 1 – 48 hours, Level 2 – 21 hours and Level 3 – 11 hours). It should be noted that reviewers will not be paid additional monies for the storage of data or postage and handling for sending assessment reports to the APVMA.

When the external reviewer submits their tax invoice they will need to add the additional number of hours to the original fee. For example, if a Level 1 assessment has taken 52 hours to complete the amount on the tax invoice will be $6,338:

- 4 hours x $168 per hour = $672;
- Level 1 fee (48 hours) = $5,666; and
- $672 + $5,666 = $6,338
2 Safe handling of APVMA sensitive information

As part of the Australian Government, the APVMA has particular responsibilities with regard to how we collect and receive sensitive information in order to fulfil our functions. The APVMA expects all external reviewers who access or hold sensitive 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
- physical items from which information regarding design, components or use could be derived.

These responsibilities are outlined in relevant legislation and policy documents that relate to the general protection and disclosure of official government information, including:

- *Crimes Act 1914* (Crimes Act)
- *Freedom of Information Act 1982* (FOI Act)
- *Privacy Act 1988* (Privacy Act)
- *Archives Act 1983* (Archives Act)
- Protective Security Policy Framework (PSPF)
- Australian Government information and communications technology security manual (ISM).

External reviewers who are dealing with APVMA sensitive information should ensure they observe the following procedural requirements from the PSPF:

- 2.1—Information access
- 2.2—Information labelling
- 2.3—Information handling, storage and disposal
- 2.4—Protecting computers
- 2.5—Portable electronic devices
- 2.6—Sending APVMA sensitive information
- 2.7—Transmitting APVMA sensitive information
- 2.8—General information

External reviewers must be prepared to accept responsibility for the safe custody of sensitive information provided to them by the APVMA. Part of this responsibility includes being aware of and adhering to the following guidelines, which are underpinned by legislation or government policy documents.

2.1 Information access

For external reviewers, it is important that APVMA sensitive information is not made available to an individual who is not listed under specified personnel in the Deed of Standing Offer, Schedule 1, clause 6.
If an individual who is not listed as specified personnel in the Deed of Standing Offer, Schedule 1, clause 6, does have access to APVMA sensitive information, it must only be for the efficient conduct of the business at hand.

It is important that external reviewers do not discuss APVMA sensitive information with unauthorised persons, or within earshot of unauthorised persons.

External reviewers working from home should recognise and accept that their immediate family, other family members and friends do not have a 'need to know' in relation to APVMA sensitive information. 'Need to know' is the principle that the availability of APVMA sensitive 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 hard copy or electronic APVMA sensitive information, either intentionally or unintentionally.

It is important for an external reviewer to understand that any breach of laws regarding the safeguarding of official information is an offence and may render an individual liable to prosecution under the Crimes Act 1914 (in particular those parts of sections 3, 7, 24A, 30, 70–74, 76A–F and 79 of the Crimes Act that relate to the reviewer’s employment with the Commonwealth), section 162 of the AGVET Code; the Australian Privacy Principles contained in Schedule 1 of the Privacy Act 1988.

The Privacy Act restricts the use and disclosure of information to which the Privacy Act applies. The Australian Privacy Principles are outlined in Schedule 1 of the Privacy Act. The following excerpts from the Agvet Code and the Crimes Act outline the specific areas of these pieces of legislation and their potential impact on an external reviewer.

The Agvet Code, section 162—improper disclosure of confidential commercial information is defined as:

(1) A person who is or has been a director, the Chief Executive Officer, or a member of the staff of the APVMA, or is or has been a consultant to the APVMA, a mediator or arbitrator appointed under this Code, or a co-ordinator designated for a jurisdiction, must not disclose, directly or indirectly, to another person any information about an active constituent for a proposed or existing chemical product, about a chemical product or any of its constituents, or about a label for containers for a chemical product, that:
   (a) the person knows to be confidential commercial information; and
   (b) was acquired by the person in the performance of such functions or duties or the exercise of such powers.

Penalty: imprisonment for 2 years.

The Crimes Act, section 3—the interpretation of a ‘Commonwealth Officer’ includes:

(c) for the purpose of sections 70, 72, 73, 74, 75 and 76: a person who although not holding office under, or employed by the Commonwealth, a Territory or public authority under the Commonwealth performs services for or on behalf of the Commonwealth, a Territory or public authority under the authority of the Commonwealth.

2.2 Information labelling

All APVMA sensitive information, regardless of its format, must have a classification label and that classification label is ‘SENSITIVE’. Documents containing APVMA sensitive information that the external reviewer may produce include:

- a registration assessment report
- a reconsideration component report
• a peer review of existing reconsideration component or registration report
• a covering letter.

All hard copies and electronic copies of APVMA sensitive information must be clearly marked ‘SENSITIVE’ 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, of a minimum height of 5 mm, and preferably red.

If a summary or covering letter does not contain APVMA sensitive 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 need to be marked.

Equipment or components (including removable electronic and optical media such as magnetic tapes, CD-ROMs, microfilms, photographs, removable disks and the like) with APVMA sensitive information stored on them must be clearly marked ‘SENSITIVE’. Please note that portable electronic devices are not included, such as laptops or smart phones.

If these items have ever been used to process or store information classified at a level higher than sensitive, the higher level is the classification that should be marked on the piece of equipment.

External reviewers should ensure that all APVMA sensitive information stored within a database or network is associated with an appropriate classification marking if it 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 APVMA sensitive information in any form. If extra copies of the document are required, they must be requested from the APVMA.

APVMA sensitive information must not be extracted from documents supplied to external reviewers with a classification of ‘SENSITIVE’, without the written approval of the APVMA, unless it is to be used in written correspondence to the APVMA.

When APVMA sensitive information is not being used, it must be stored in a lockable filing cabinet. The keys to the filing cabinet must be secured.

When the external reviewer has finalised an assessment, they are expected to send all APVMA sensitive information back to the APVMA together with the final assessment report and invoice.

### 2.4 Protecting computers

Computers have intrinsic value and therefore are at risk from theft, and the loss of both the equipment and any APVMA sensitive information that has been stored on the computer need to be taken into consideration. Computers, including laptops, must be given the same level of protection as similarly classified hard copy 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 that 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 precautions in place:

- they are password protected
- the passwords are safeguarded and not shared unnecessarily
- any unnecessary file sharing functionality is removed.

You should only store APVMA sensitive information on a data stick rather than on the hard drive of your computer or laptop. If the hard drive is used, you should partition the hard drive so that APVMA sensitive information can be quarantined, and ensure that the partition is password protected. When work for the APVMA is completed, you should delete the classified files from systems, defragment hard drives and reformat data sticks.

**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 following these guidelines:

- use 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**

Follow these guidelines:

- ensure anti-virus software is installed on all computers or laptops
- ensure system users do not have the ability to disable the virus scanner
- check vendor virus pattern signatures for updates daily or the first time you log in after a pause in use of 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 repair of hardware**

If possible, use an appropriately cleared and briefed technician for the maintenance and repair of hardware products containing APVMA sensitive 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 sensitive information is not disclosed.
It is advised that off-site repairs be avoided. If off-site maintenance is required, remove all APVMA sensitive information and make sure the computer or laptop is sanitised before permitting the hardware to be moved off-site.

It is recommended that external reviewers who use laptops use soft labelling where possible to reduce their visibility and likelihood of theft, for example any identification labelling should be on the inside of the laptop where it can’t be seen rather than on the outside.

It is recommended that external reviewers affix an additional label to the laptop asking finders to hand the equipment into 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 sensitive information it is recommended that an external reviewer who 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

Portable electronic devices (PEDs) include, but are not limited to personal digital assistants, mobile phones, smart phones, two-way email devices and digital audio players or recorders.

Similarly to computers, 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, physical or virtual could:

- gain access to APVMA sensitive information stored on these devices if they are lost or stolen
- see information while a PED is in use or overhear a conversation while voice calls are being made in an unsecured environment.

External reviewers using PEDs must NOT store any APVMA sensitive information on them.

External reviewers using PEDs must not conduct telephone conversations discussing APVMA sensitive 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 devices in a physically protected area.

It is recommended that external reviewers who use PEDs use soft labelling where possible to reduce their visibility and the likelihood of theft.

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 or destroy non-agency-owned PEDs in the case of an APVMA sensitive information and communications technology security incident.

2.6 Security Arrangements

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 possibly related to home-based work or not, such as a break-in, renovations, or the like.

2.7 Sending APVMA sensitive information

When the final assessment report is finalised, the external reviewer is required to send an electronic copy to the APVMA.

When sending hard copy APVMA sensitive information (for example, data) it is important that it is securely wrapped. APVMA sensitive information sent by envelope should be double enveloped, which is achieved by using two new opaque envelopes. The inner envelope MUST be marked ‘SENSITIVE’. Both inner and outer envelopes must always be sealed. The outer envelope MUST NOT indicate that there is APVMA sensitive information in the inner envelope.

If the APVMA sensitive information being sent is too large for an envelope, it should be put in a suitable container that does not indicate that it contains APVMA sensitive information. The container must be securely closed so that it does not open in transit.

If the APVMA sensitive information is delivered by hand from the external reviewer to a known APVMA staff member, the envelope should be addressed to that person as well as being double enveloped. Acceptable delivery methods are those by Security Construction and Equipment Committee–endorsed overnight couriers. The APVMA preferred supplier is Toll.

2.8 Transmitting APVMA sensitive information

Faxing

External reviewers MUST NOT send APVMA sensitive information by fax to the APVMA as the phone line is not secure.

Emailing

It is not possible for the APVMA to send or receive emails containing sensitive information to or from anyone not connected to Fedlink. Fedlink is the Australian Government’s secure email service. For individuals who do not have access to Fedlink, the APVMA uses a secure messaging system called McAfee Email Gateway. This secure email system will permit ‘name@apvma.gov.au’ email addresses to send APVMA sensitive information to people registered on McAfee Email Gateway. This secure system should include applicants, manufacturers, external reviewers and the like.

APVMA staff members are able to send emails containing APVMA sensitive information to specifically nominated people, instructing them that they can receive APVMA sensitive information via a secure website after an external reviewer has registered on the website. Only people who receive this initial email will be permitted to use the secure system.

An external reviewer does not have a name@apvma.gov.au email address, and must not forward emails that contain APVMA sensitive information to any other individual or organisation. External reviewers should be aware that the automatic forwarding of an email to other persons outside of the APVMA could result in the recipient seeing information for which they do not have a need to know, or information that is considered private, according to the Australian Privacy Principles as outlined in Schedule 1 of the Privacy Act. This means external reviewers are only permitted to send emails containing APVMA sensitive information to the APVMA.
External reviewers MUST NOT send or receive emails from the APVMA using a web-based public email service (such as Hotmail or Bigpond).

External reviewers who are able to send emails to the APVMA 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. For example, when sending an assessment report that contains confidential commercial information to the APVMA via email, a ‘SENSITIVE’ protective marking should be used.

2.9 General information

At the close of each working day, external reviewers should take precautions to ensure that hard copy and electronic APVMA sensitive 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. This should include:

- logging off from all systems and switching off the computer or laptop
- ensuring that all APVMA sensitive information is locked away and the key is secured
- ensuring that laptops and other electronic devices storing APVMA sensitive information are locked away and the key is secured
- ensuring there is no APVMA sensitive information in wastepaper bins
- ensuring that whiteboards and other displays do not show any APVMA sensitive information (please note that special care needs to be taken with electronic whiteboards)
- ensuring that windows and doors in the work area are locked and that the key is secured.
## Attachment A: Official order

<table>
<thead>
<tr>
<th>Official order/contract details</th>
<th>[insert APVMA contract number] for [insert the services]</th>
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<tbody>
<tr>
<td>Under Deed of Standing Offer (Head Agreement for services)—[insert the Deed of Standing Offer number]</td>
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<table>
<thead>
<tr>
<th>[Program name]</th>
<th>[Contractor] [ABN: ]</th>
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<td>[Address]</td>
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APVMA liaison officer:
[……………….position], currently [……………….name]
Telephone: .................
Facsimile: .................

Contractor liaison officer
[……………….position], currently [……………….name]
Telephone: .................
Facsimile: .................

This official order is placed pursuant to and subject to the terms and conditions of the Deed of Standing Offer (Head Agreement for services) between the APVMA and [insert name of contractor] dated [insert date].

If you wish to provide the services to the APVMA, please sign this official order and send it to the APVMA. If the APVMA wishes to accept your offer to provide the services, it will execute the official order and return a copy of the executed official order to you. You must not supply the services until after you have received the copy of the executed official order from the APVMA.

### Summary description of services required:

$XXX (cost) plus $XXX (GST) totalling $XXX TOTAL COST (GST inc.)

<table>
<thead>
<tr>
<th>Services to commence on</th>
<th>.../../. ....</th>
</tr>
</thead>
<tbody>
<tr>
<td>Services to be completed by</td>
<td>.../../. ....</td>
</tr>
</tbody>
</table>

Invoices are to be issued to the APVMA liaison officer named above.

For APVMA purposes only:

For fees and rates, see item 3.

<table>
<thead>
<tr>
<th>Cost centre:</th>
<th>APVMA contract #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Charge code:</td>
<td>APVMA purpose only</td>
</tr>
</tbody>
</table>
1. **The services, subcontractors and contract material**

   [This part will include a description of the services, clearly detailing exactly what the APVMA requires the contractor to do and the outcomes and contract material that the APVMA expects the contractor to produce, including the reporting requirements. It will also include details of any subcontractors that the APVMA has agreed can undertake any part of the services. This part will also specify any relevant Australian standards or Commonwealth and industry standards and guidelines that the APVMA requires the contractor to comply with or meet in delivering the services.]

2. **Timeframe**

   [This part will specify the times for performance of the services and the period over which the services are to be performed.]

3. **Fees, allowances and costs**

   [This part will include the fees payable for the performance of the services calculated in accordance with schedule 3 of the deed (including any hourly or daily rates payable) and, if applicable, any allowances or costs associated with the performance of the services calculated in accordance with schedule 3 of the deed. This part will also stipulate whether the APVMA will pay fees by instalments, and if so, the deliverables to which payments will relate or the instalment intervals. Any special requirements for the submission of invoices by the contractor will be detailed here.]

4. **Insurance**

   [This part will stipulate the insurance that the contractor is required to maintain.]

5. **Specified personnel**

   [This part will specify the names of specified personnel who the APVMA has agreed are to undertake the work.]

6. **APVMA material (if applicable)**

   [This part will include the details of any material to be provided to the contractor by the APVMA and any special requirements relating to the use, storage and retention by the contractor of that APVMA material.]

7. **Existing material**

   [This part will stipulate any existing material that the contractor will use in development of the contract material and that the APVMA will obtain a licence to use in conjunction with the contract material. This will be discussed with the contractor, as it is the contractor’s (or a third party’s) existing material that will be listed here (if any).]
8. **Contract material (if applicable)**
   [This part will include any additional requirements or directions relating to the handling and retention of contract material.]

9. **Confidential material (if applicable)**
   [This part will include any additional requirements or directions relating to the handling and retention of the APVMA’s confidential information.]

10. **Commonwealth assistance (if applicable)**
    [This part will include any facilities, assistance or both that the APVMA has agreed to provide to the contractor.]

11. **Other terms and conditions (if applicable)**
    [This part will specify any other terms and conditions, which the parties agreed to, if applicable.]
This contract/official order is **SIGNED** as a contract.

**SIGNED** for and on behalf of the **AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY**

ABN 19 495 043 447 on:

__________________________

Date

by:

______________________________

Printed name of signatory

Signature

______________________________

Position of signatory

in the presence of:

______________________________

Printed name of witness

Signature of witness

**SIGNED** by …………………………… [insert name of contractor], ABN ………………..… [insert contractor’s ABN], in accordance with subsection 127(1) of the Corporations Act 2001 on: [This signature block is only appropriate when the contractor is a company incorporated under the Corporations Act with several directors or a director and secretary who are separate persons.]

__________________________

Date

by:

______________________________

Printed name of director

Signature of director

and:

______________________________

Printed name of director/secretary

Signature of director/secretary
### Revision history

<table>
<thead>
<tr>
<th>Revision date</th>
<th>Description of revision</th>
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<tbody>
<tr>
<td>01/07/09</td>
<td>First edition</td>
</tr>
<tr>
<td>01/07/10</td>
<td>Second edition</td>
</tr>
<tr>
<td></td>
<td>Updates to the manual—sections 1.3, 1.5 and Attachment A—APVMA work order.</td>
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<tr>
<td>01/07/11</td>
<td>Third edition</td>
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<tr>
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<td>Update to the manual—section 1.3.</td>
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<tr>
<td>10/12/12</td>
<td>Fourth edition</td>
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<td>Updates to the manual—sections 1.2, 1.3, 1.4, 1.5, 1.6, 1.8, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, Attachment A—APVMA Work Order, Attachment B—External Reviewer Declaration.</td>
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<tr>
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<td>Additions to the manual - Attachment D—Survey.</td>
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<tr>
<td>01/07/14</td>
<td>Fifth edition</td>
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<td>Updates to the manual—sections 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, Attachment A—Official order, Glossary and Revision history</td>
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