



APVMA Application Requirements for
Data Protection, Application summaries and
Advice summaries

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1.0 Introduction

The *Agricultural and Veterinary Chemicals Code 1994* (the Agvet Code) requires the APVMA to do, or not do certain things in relation to information supplied with applications. This includes:

1. Data Protection – limitations on how the APVMA can use information in making certain decisions;
2. Early Disclosure – publishing application summaries once an application has been accepted for assessment; and
3. Summaries of Advice – publishing a summary of the advice provided by other Government departments and agencies, and other specialists the APVMA consults, in relation to applications which are granted.

This document sets out what is required of applicants with respect to the above three matters. These requirements are only relevant for applications for active constituents, products and labels. They are not relevant to applications for permits.

A detailed background on the data protection and transparency provisions of the Agvet Code can be in the document 'Data Protection, Application Summary and Advice Summary Provisions of the Agvet Code and the Agvet Chemical Industry' available from the Data Protection page of the APVMA website.

2.0 Requirements

Before an application is submitted to the APVMA, applicants are required to undertake a few steps depending on the purpose of the application. The requirements include:

2.1 Information on Application Forms

The three main application forms (product registration and variation, administrative variations and active constituents) include one or more of the following requirements:

a) Application Purpose and Description of Use

The APVMA is required to publish a summary of certain applications that have passed preliminary assessment and have been accepted for evaluation (i.e. Early Disclosure). Application summaries are required to include a description of the application including the proposed use of the active and or product (a 'purpose and description' statement). To aid applicants in providing this information in the required manner, a guideline for the preparation of a purpose and description statement is available under Data Protection on the APVMA website.

b) New Data

Due to the need to publish details of what information the APVMA required and relied on in accepting and granting an application respectively, applicants are required to complete a data list. The details of the data list are discussed below.

A data list is required whenever 'information' (e.g. data) is provided with an application and it should be provided in both electronic and hard copy to allow the APVMA to process the application in an efficient manner. The application form requires the applicant to inform whether a data list has been provided and if so, whether the electronic copy has been emailed or provided on a disk or CD with the application.

c) Protected Data

To determine whether the APVMA is required to use protected data for a particular application, applicants are required to nominate the respective reference products or active constituents and via the APVMA's website, check whether there is any protected data associated with the products or active constituents.

Where reference products or active constituents are relevant to an application, applicant's are required to use the PUBCRIS facility to check if there is any application protected data¹ associated with the reference product or active constituent. In addition, to applicants checking for the presence of 'application' protected data, applicants should also check whether there is any Chemical Review or TRIPS protected data in relation to the application being made. A list of active constituents and products that have chemical review protected data and a list of active constituents subject to TRIPS protection is available under Data Protection on the APVMA website.

Undertaking these checks before making the application will save both the applicant and the APVMA significant time and resources, as applications will not be accepted for assessment without the necessary access to all protected data.

d) Authorising Parties

With respect to application protected data, applicants must ensure the APVMA receives the required consent for use from the necessary authorising parties to allow the APVMA to access the protected data for the application at hand. The APVMA has standard format Consent For Use letter templates available under Data Protection on the APVMA website. These templates must be used to satisfy the APVMA that the correct access has been granted.

¹ Application protected data is the APVMA term used for data protected under the scheme associated with the US Free Trade Agreement which commenced 1 January 2005.

When referencing protected data, applicants are required to list the relevant authorising parties and state how the consent is being provided to the APVMA. For further details on Authorising Parties and Consent For Use letters see below.

e) Distinct Prescribed Uses

Where an applicant is proposing that a product label is including distinct prescribed uses², applicants are required to nominate the relevant crops/animals/situations on the product application form. Further information on distinct prescribed uses and how they can extend the period of protection for certain protected data can be obtained from the document 'Data Protection, Application Summary & Advice Summary Provisions of the Agvet Code and the Agvet Chemical Industry' which is available under Data Protection on the APVMA website.

2.2 The Data List

When providing information with an application, the APVMA requires that the application include a list of data in accordance with the format specified in the published guidance material (see APVMA website). The APVMA has two templates available for applicants to choose from to create an application data list.

One template includes in-built macros which allow fixed choices to be made for certain information and the other will require manual entry of all fields as per a standard table in a word processor type document. The benefits of the macro version are that it will allow quick entry of fields by applicants, the text will not have errors facilitating more rapid electronically upload the information into the APVMA's databases.

The data list templates and instructions for their use can be found under Data Protection on the APVMA website. If an application does not include a data list or the list is missing information or contains errors, the application will be considered deficient. If an applicant fails to provide the list in the required format the APVMA will reject the application.

2.3 Consent For Use Letters

As discussed above, applicants referencing protected data must ensure the APVMA receives the appropriate consent for use to access that data, from the relevant authorising parties. Templates specifying the required format for the consent for use letter are available under Data Protection on the APVMA website. If a Consent For Use letter is not provided from the required authorising parties, is in the wrong format or is incomplete the application will be considered deficient. If an applicant subsequently fails to provide a Consent for Use letter in the required format the APVMA will reject the application.

Only one Consent For Use letter per Authorising Party per product is required for the life of the product, as once consent has been given it cannot be withdrawn. Authorising Parties are therefore encouraged to ensure that any commercial arrangements between them and applicants are framed accordingly.

2.4 Presentation of Data

Data should be presented in a logical format that is easily reconcilable with the data list. Where possible it is preferable for applicants to use the volume and/or page number where the document/study can be found in the data package as the applicants reference number in the data list. This assists the APVMA to locate the piece of information when considering the application.

² A 'distinct prescribed use' is a non-major crop use or a non-major animal use prescribed by Regulation 22A and Schedule 3A of the *Agricultural and Veterinary Chemicals Code Regulations 1995*.

The title used for each piece of information submitted and included in a data list must be the original unedited title given to the item of information by the author. The information submitted must be complete and extracts of experimental reports/studies or report/studies with information obscured or hidden by blanking out will not be accepted as the APVMA has no way of determining if the hidden or omitted information is relevant to its consideration of the study or report. Where studies, reports or alike are submitted with sections of information obscured the APVMA will exercise its discretion under section 159 of the Agvet Code to require the full text to be provided in order to be satisfied that the obscured information is not relevant to the application, or to its assessment of the information. Applications containing studies or reports with obscured information will be treated as deficient until the complete document is provided.

3.0 Confidential Commercial Information

The APVMA's 'Guideline to the type of information the APVMA will routinely publish in relation to applications', available under Data Protection on the APVMA website, describes the type of information that the APVMA is required to publish in relation to applications. The guideline includes the definition of 'confidential commercial information' as provided by the Agvet Code. Applicants should ensure they are familiar with this guideline.

Where the APVMA has granted an application involving an active, product or label and the APVMA has relied on advice provided by another Government body or specialist consultant in doing so, the APVMA must publish a summary of that advice. This is a requirement of the Agvet Code. Should an applicant have concerns about the type of information that may be published, please consult the guideline and if necessary discuss the matter with the APVMA.

4.0 Data Protection Associated Documentation

Where an application involves data that is eligible for protection or is reliant in protected data, the applicant should expect the following documents:

4.1 After acknowledgement of application

Where an application includes submitted data and the APVMA writes to the applicant notifying the application has passed preliminary assessment (screening) and been assigned, a copy of the data list, showing what data was required for the application, will be included. This same list will be published to the website as part of the application summary.

4.2 Advice Reports

Where the APVMA has received an assessment report from an advising agency, a copy will be presented to the applicant for any technical responses as usual. However, as these reports (minus CCI) are publicly available, applicants will also need to check the report for any CCI that has not been moved to an appropriate CCI appendix.

Advice reports show what data was relied on by the agency and will also include an executive summary of their assessment which will be used by the APVMA in publishing Advice Summaries to the APVMA website.

4.3 After granting an application

Where an application has been granted and there is associated protected data as a result, the APVMA will include with the notice, a copy of the data list showing all

protected data. Where an application has been withdrawn or refused, no data protection is provided and therefore a list will not be sent to the applicant.

4.4 Other actions

The APVMA provides a consolidated list of protected data per application, per product, in the PUBCRIS product search area of the APVMA website.

5.0 Some Frequently Asked Questions

5.1 Does information required for permit applications gain protection?

No. The current data protection provisions relate only to data provided for applications for new active constituents, new products and labels or variations to products and labels.

5.2 Can permit applications reference active constituents or products with protected data to meet requirements?

Yes. The new data protection provisions only prohibit the APVMA from using protected data to make decisions on applications for new active constituents, new products and labels or variations to products and labels.

5.3 Are there other exceptions to the use of protected data?

Yes. The APVMA can use protected data in the following circumstances:

- When the Authorising Party provides a Consent For Use letter;
- When the use of the data is in the public interest;
- When the data causes the APVMA to reconsider a current or proposed active constituent approval or product registration; and
- When there is identical information or information to the same effect, which is not protected.

5.4 What happens when there is accidental disclosure of protected data?

If the APVMA or any of its advice providers disclose protected information in relation to an application for a product containing a new active and as a result a subsequent application for a second similar product includes unauthorised use of that data, the APVMA is prohibited from using that data for a period of 10 years to grant that application.

5.5 What decisions can be reviewed by the Administrative Appeals Tribunal (AAT)?

Under the new arrangements the AAT will be able to review decision by the APVMA to:

- Use protected data when in the public interest; and
- Defer, withdraw or reject an application for not meeting application requirements.

The decision on whether a particular piece of information was relied on by the APVMA is not reviewable by the AAT.

5.6 What about applications submitted prior to 1 January 2005?

Any data provided with an application that was submitted prior to 1 January 2005 will not be eligible for protection. This includes data submitted after 1 January 2005 as part of the application.

5.7 What if two study reports have identical titles?

Where two pieces of information have identical titles (e.g. they may be part of a series of duplicate tests), each report must have a different Applicant Reference Code. The second report will not be considered a duplicate entry and will not be deleted from the data list.

5.8 Are Consent For Use letters product specific?

Where a consent for use letter only provides support for one product, the same applicant for another similar product will require an additional consent for use letter. Where a product has been registered using a particular consent for use letter and the registrant applies to repack that product, an additional consent for use letter will be required.

6.0 Glossary

6.1 Information Definition

The APVMA is using the following definition of information and data with respect to the data protection provisions and the APVMA's associated requirements:

- a report describing one or more tests, analyses, trials or studies (eg, a stability trial, toxicology study, metabolism study, residue processing study, worker exposure study, ecotoxicology study, efficacy trial etc);
- a report summarising information necessary to meet APVMA requirements (eg, a report summarising the toxicological properties and case histories of a particular active constituent with respect to target animal safety);
- a description of a method of analysis (including validation methods); and
- an expert opinion provided on a data requirement by someone other than the applicant.

Other information provided to the APVMA will not be required to be listed and therefore will not be used in Application Summaries or Advice Summaries. However, where required, this information will be considered Confidential Commercial Information (CCI) and so not released unless in accordance with the CCI guidelines.

6.2 Authorising Party

The Agvet Code defines an authorising party as:

'a person who would be entitled to bring an action for breach of an obligation of confidence if the information were disclosed by someone else to the APVMA for the purposes of this Code without the person's permission'.

A 'person' can be an individual, a number of individuals, a limited liability company or a group of limited liability companies (e.g. a taskforce). The authorising party need not reside in Australia. The APVMA can only accept Consent For Use letters from the nominated authorising party. This does not include subsidiary or parent companies of the authorising party.