



Data Protection, Application Summary and  
Advice Summary Provisions of the Agvet Code  
and the Agvet Chemical Industry

February 2007

## **Purpose**

On 1 January 2005 the way that the APVMA could use scientific information provided in connection with applications it receives changed. This came about as a result of wide-ranging changes required with the implementation of the Free Trade Agreement with the United States.

This document outlines the effect of the changes, what is now known as the data protection, early disclosure (application summary) and transparency (advice summary) provisions of the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code).

## **Introduction**

There were three major changes to how the APVMA uses the information provided with certain applications as a result of the implementation of the US Free Trade Agreement. The changes, which took effect on 1 January 2005, fell into the categories of:

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. Transparency or *summaries of advice* – publishing the advice provided by other Government departments and agencies, and other specialists the APVMA consults, in relation to applications which are granted.

## **1. Data Protection**

The data protection provisions introduced on 1 January 2005 relate only to information provided with applications for active constituents, products and labels. They do not have any impact on the existing system for information provided for Chemical Reviews undertaken by the APVMA.

Where applicants provide information with an application, the APVMA is restricted from using it for certain decisions without the permission of the *Authorising Party*<sup>1</sup>. Essentially, the data protection provisions apply to the following four situations:

- (a) Screening;
- (b) Evaluation;
- (c) After the application is approved or granted (i.e. new active, product or label in the market); and
- (d) Section 161 data

### ***Some qualifications***

Pre-approval protection (Screening and evaluation): While an application for an active or product is in screening or is being evaluated, the APVMA is restricted from using that information for another application relating to an active or product (not permits) as well as any Chemical Reviews currently in progress.

After application approval (or market protection): Once an application has been finalised, all information that the APVMA relied on to be satisfied to approve/grant the application, effectively becomes protected data. What this protection means, is that the APVMA is limited from using that information to make a decision on another application (except for a permit) or a Chemical Review

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<sup>1</sup> The *Authorising Party* is the person or persons from whom consent for use must be obtained by a third party for the APVMA to use 'protected data'. In essence the 'authorising party' is the owner/controller of the information

without the consent of the Authorising Party (or when one of the other exceptions apply, see below).

The length of protection depends on the purpose of the application. Appendix 1 provides details of the protection periods for application data and extending the period of protection.

### ***Exceptions allowing use of protected data***

The APVMA can use protected data when making a decision on an application or chemical review if one of the following conditions is met (see Figure 1 for graphic representation).

1. **Consent for use.** The APVMA can use protected data when consent for use has been provided by the authorising party for that data. The consent remains valid even if it is withdrawn or was fraudulently provided. Any disputes as to the validity of the consent will be a matter for the parties. However it is a criminal offence to make a false statement to the APVMA.
2. **Public interest.** The APVMA can use protected data when it is in the public interest to do so. Public interest can include a range of things but will include when the data indicates an undue risk to human health and the environment. The APVMA currently has similar powers in relation to Chemical Reviews. Data owners will receive a notice indicating the APVMA's intention to use the information in the public interest and the data owner has the right to appeal the use via the Administrative Appeals Tribunal (AAT). There is no right of review where the APVMA considers it is necessary to use the data due to an imminent risk to human health or the environment.
3. **Unfavourable to another application.** The APVMA can use protected data when considering another application involving an active, product or label where the APVMA considers the data demonstrates the second application is unable to meet requirements with respect to safety to people or the environment, or the product is ineffective.
4. **Identical information.** The APVMA can use protected data when there is identical information available that is not protected (eg. publicly available information or information that was previously protected but for which the protection period has expired). Information that is declared to be publicly available will not receive protection. Similarly, information that is identical to unprotected information held by the APVMA will not receive protection. Note, it is the applicant's responsibility to indicate if submitted information is publicly available, or to their knowledge, has previously been submitted to the APVMA. There are penalties for providing a false declaration to the APVMA.
5. **Ineligible applications.** The APVMA is not limited from using data provided with one of the following types of applications as these applications are ineligible for data protection:
  - a. an application for an active constituent which at some time in the past had been an approved active (e.g. either by the APVMA, NRA or State Government) or had been an active constituent in a registered product (either by the APVMA, NRA or State Government). That is if the active has already existed (i.e been approved) previously in Australia then it can not be considered a new active (and gain protection), but is considered a 'previously endorsed active constituent';
  - b. an application to vary an active constituent approval. Information provided with an application to vary the particulars or conditions of an approval does not gain protection;
  - c. an application for registration of a companion animal product where that product does not contain a new active (i.e. includes a previously endorsed active constituent).

Companion animals products are defined as products for use on, or administered to, non-food producing animals and any food producing animals defined by the regulations. Horses are companion animals;

- d. an application to vary the registration of a companion animal product;
- e. an application to approve a label of a companion animal product where that product does not contain a new active;
- f. an application to vary a label of a companion animal product.

### ***What is required of applicants for Data Protection?***

Application requirements relating to data protection can be grouped into two types:

1. requirements when providing data; and
2. requirements when referencing data.

The following is a general description of what is required. Further details are available in the guidance document *Application Requirements for Data Protection, Application Summaries & Advice Summaries* which is available under Data Protection on the APVMA website.

#### **Requirements when providing information**

When providing new data with an application, applicants are required to complete a data list, including all data submitted. Data list templates and detailed instructions regarding how to provide a data list in the required format are available under Data Protection on the APVMA website.

Both hardcopy and electronic versions of the data list are required.

The APVMA will use this information to generate application summaries and to produce the required documentation for assessment.

#### **Requirements when referencing information**

For all applications that need to reference information held by the APVMA in order to satisfy the APVMA's full data requirements, applicants will need to consider:

- Do the reference products/active constituents have associated protected information, and if so
- Do I have the necessary consent for use from the authorising party?

Where consent for use is required applicants must organise this with the authorising party prior to submitting the application. Applications not containing any necessary consent for use cannot proceed and may be rejected.

To assist applicants determine the protected data status of any reference products/active constituents, a list of any application protected data associated with a product/active constituent can be accessed via the PUBCRIS search facility, available from the APVMA website. The list includes the data reference details, including the authorising party and their contact details. The list also indicates the number of the application to which the data relates, allowing easy identification of the relevant Advice Summary (see below).

To assist applicants provide the consent for use in the required format, consent for use letter templates are available under Data Protection on the APVMA website.

## **2. Early disclosure**

For most applications, the APVMA is required to publish a 'summary of application' shortly after the application has been accepted for assessment after passing screening ('acknowledged'). The purpose of early disclosure is to increase the transparency of the type of information required by the APVMA from applicants. It also allows the APVMA to publicly acknowledge if a certain application has been made.

One of the considerable benefits of this provision is that other Government authorities with whom the APVMA deals, such as Food Standards Australia New Zealand (FSANZ) and the Office of the Gene Technology Regulator (OGTR) will be able to disclose the existence of an application to allow other related regulatory actions to occur. This can significantly reduce the regulatory time burdens for certain products.

The type of applications to which early disclosure applies include those for new actives, products and labels and applications involving variation products and labels, where the variation involves a change to the use, supply or disposal of the product.

The summary will include details specified in the Regulations. The Regulations require different application summaries depending on the type of application. They include different combinations of the following details:

- applicant name
- application number
- active constituent name and number
- product name and number
- application purpose and description of active constituent or product use
- a list of what data was provided with the application and considered to be required by the APVMA; and
- the relevant reference active constituent and or product names and numbers.

#### ***What is required of applicants for early disclosure?***

To allow the APVMA to publish application summaries for early disclosure as efficiently as possible, applicants are required to provide a data list in the required format (see above) whenever data is submitted with an application and a 'purpose and description' statement. The APVMA application forms prompt for the necessary information (such as the purpose and description statement) and a guideline to assist applicants prepare an appropriate 'purpose and description' statement is available under Data Protection on the APVMA website.

### **3. Summaries of Advice**

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 (e.g. Australian, State or Territory government department, authority or organisation), or a person contracted by the APVMA, the APVMA must publish a summary of that advice.

The summary will include details specified in the Regulations. The Regulations require similar details as for application summaries, however also require:

- a summary of the assessment undertaken to provide the advice; and
- a list of the information relied on in providing the advice.

Confidential Commercial information (CCI) will not be included in the summary of advice.

A detailed guideline to the type of information the APVMA will routinely publish in relation to applications is available under Data Protection on the APVMA website. That guideline includes the Agvet Code definition of CCI.

#### ***What will be required of applicants for summaries of advice?***

The APVMA uses the executive summaries of advice reports to generate summaries of advice. Applicants should consider the executive summaries of advice reports as soon as possible after a copy has been provided to them and advise the APVMA if they consider certain information to be CCI.

In addition to advice summaries, advice reports may be publicly available. Although CCI information will only be included in these reports in a removable CCI attachment (that will not be

made publicly available), applicants are required to check the advice reports to satisfy themselves that CCI information not included in the report body.

### **Miscellaneous provisions**

The Agvet Code includes additional matters relevant to the APVMA that may be of importance to industry. For the sake of restricting this document to matters that the APVMA is likely to encounter these additional provisions have not been discussed in any detail. The APVMA does how

ever ensure the requirements of these provisions are met by the necessary business operations and is happy to discuss them with industry as required. They involve matters such as:

- other rules regarding the public interest exception;
- requirements of the APVMA on disclosure of protected information;
- protection of the information in the event of an accidental or unauthorized disclosure;  
and
- decisions that are reviewable to the AAT.

## Appendix 1 – Protection periods for application data

	<b>Data provided with this type of application</b>	<b>Number of years protection*</b>
1	Application to approve a new active constituent (i.e. one never previously approved or present as an active in a registered product)	8
2	Application to register a product containing a new active as described in item 1 above – where the application for the product had passed screening (i.e. accepted for evaluation) before the active in item 1 had been approved.	8
3	Application to register an agricultural chemical product other than as described in 2 above	5
4	Application to register an veterinary chemical product other than as described in 2 above	3
5	Application to vary an agricultural chemical product and or label	5
6	Application to vary an veterinary chemical product and or label	3

\* The protection period starts from the day the application is granted

### ***Extending the Period of Protection – Prescribed Uses***

It is possible to extend the protection period for certain data when the following conditions are met. Data that has received 8 years protection (i.e. items 1 and 2 of the above table) will be extended by 1 year for each 5 distinct prescribed uses that meet the following requirements:

- the distinct prescribed use is on an approved label of a product as described in item 2 of the table;
- the application to include the distinct prescribed use on a label of the a chemical product (an extension product) was accepted for evaluation before the end of the 6<sup>th</sup> year of protection of the data associated with the new active;
- all 5 of the distinct prescribed uses are specified in the relevant regulation by the time the application including the 5<sup>th</sup> use is granted. Regulation 22A of the Agvet Code Regulations determines what is a distinct prescribed use by requiring the use is:
  - a non-major use as listed in the table attached to the Regulations (essentially minor crops and minor animal species); and
  - data has been provided specifically on that non-major use (i.e. the applicant is not extrapolating from data provided on other uses to satisfy APVMA requirements for the distinct use); and
  - the data was required for the type of application involved and was relied on by the APVMA to be satisfied to grant the application including the distinct use on the label; and
  - the use is specified on the label. Note, if the use is a food or non-food crop, then the use can be specified on the label via either the crop or the associated crop group as specified in the Regulations.

Importantly, the period of protection cannot exceed 11 years.

### ***Section 161 data (notification of new information to the APVMA)***

Section 161 requires that when a registrant, approval holder or a person acting on their behalf, becomes aware of any information that is relevant to the approved active or registered product, they must give that information to the APVMA.

If section 161 information is provided for a product (whose application for registration was made after 1 January 2005), the APVMA is limited from using the information for the purpose of making a decision on another person's application involving an active, product or label or a decision in a review for:

- a period of 5 years if the product is an agricultural chemical product; or
- a period of 3 years if the product is a veterinary chemical product.

The protection period starts from the time the information was received.

### **Contacting the APVMA on data protection and other associated matters.**

If you have any questions on any of the above or related information, please contact the APVMA via the Agricultural Products Coordinator, Veterinary Products Coordinator or the Enquiry Line. For details see *Contact us* on the APVMA website ([www.apvma.gov.au](http://www.apvma.gov.au)).