

NOTICE

Data Protection: Authorising Party Options in Data Lists

The 'authorising party' of information eligible for data protection, is the person or persons from whom the applicant for a subsequent application must obtain consent, if the APVMA is to use that data for that subsequent application.

In essence the 'authorising party' is the owner/controller of the information.

The purpose of this notice is to advise that additional authorising party options have been added to the APVMA data list template to allow applicants to accurately identify information that has previously been submitted to the APVMA when resubmitting it with subsequent applications.

Resubmission of information

Unless directly imaging a use or claim from a reference product, applicants are generally required to provide copies of all data relevant to their application, irrespective of whether or not they may have previously submitted that information to the APVMA. Experience has demonstrated that many applications are supported by data that has previously been submitted with another application. Such data may have been submitted prior to 1 January 2005, when the current application data protection provisions took effect, or after the provisions were in effect.

Information submitted to the APVMA in connection with an application made prior to 1 January 2005 cannot be eligible for data protection because the APVMA holds a copy of that information whose use is not limited. Similarly, information submitted in connection with an application made after 1 January 2005 that was not *required* by the APVMA for the purposes of assessing the application, or was not *relied on* by the APVMA to grant the application is not eligible for data protection because the APVMA holds a copy of that information whose use is not limited.

Data protection is only applicable to new information provided in connection with applications made after 1 January 2005 for approval or registration, or to vary an existing registration, if the information is *required* and subsequently *relied on* to grant the application.

Previously-submitted information may either be not eligible for protection or already subject to an existing data protection period when resubmitted with a subsequent application.

Authorising party options

The APVMA data lists that have been in use until this point have had the capacity to record the authorising party as 'Applicant', 'Other Party' or 'Public Domain'. Data identified with an authorising party of 'Applicant' or 'Other party' is eligible for data protection¹ whereas 'Public domain' data is not eligible for protection.

Although a significant proportion of previously-submitted information that has been resubmitted to date is not eligible for data protection, the APVMA understands applicants' concerns regarding classifying it as 'Public domain' because the information is often not actually freely available in the public domain and is often of commercial value. In addition,

¹ Except for companion animal products containing a previously endorsed (approved) active constituent

the management of previously-submitted information that is already subject to a protection period in data lists has posed difficulties, because to this point there has been not been an easy way for applicants to identify this information and link it to the existing data record and protection period.

To allow applicants to accurately identify information that has previously been submitted, the APVMA has added two additional options to the authorising party field of the data list:

- ‘Pre Sub, Not Protected’ - to identify information that has been previously submitted but that is not eligible for protection; and
- ‘Prev Sub, Protected’ - to identify information that has previously been submitted and is subject to an existing protection period.

Data identified as ‘Pre Sub, Not Protected’ will not receive data protection, even if *required* and *relied on* to grant the application with which it is submitted for the reasons outlined above. Where data is identified as ‘Prev Sub, Protected’, applicants must enter the ‘APVMA data number’ in the data list that the piece of data was assigned by the APVMA when it was previously submitted. The APVMA data number will be apparent from the ‘APVMA data list’ that the applicant will have received for the application with which the data was originally submitted. Alternatively it may be obtained from the PUBCRIS record of the relevant registered product or approved active constituent.

The actual ‘authorising party’ of resubmitted data identified as ‘Prev Sub, Protected’ in a data list (i.e. the person who may give consent for its subsequent use) will remain as it is listed in the APVMA data list associated with the application under which the data was originally submitted.

It is important to note that it is the applicant’s responsibility to ensure that data is accurately identified and that data an applicant knows they have submitted previously, is recorded appropriately in the application data list. Criminal penalties exist for providing false information to the APVMA.

Applicants should exercise care when resubmitting information that is subject to an existing data protection period. If the resubmitted copy is not *required* or not *relied on* by the APVMA to grant the subsequent application, the impact will be that the resubmitted copy will not be protected (ie its use will not be limited) and hence it may subsequently be referenced without consent. This effect has previously been explained in previous gazettals (Gazette APVMA 6, 6 June 2006, Page 27).

Actions required

The new data list template is available for download from the data protection page of the APVMA website. The data list instructions (including instructions regarding the download of the data list template) have been revised and are also available from that page. Applicants should use the most recent version of the data list template from the APVMA website for each application they prepare.

The APVMA will continue to accept the preceding version of the data list version (ie the version without the new authorising party options), therefore applicants who are presently preparing applications using that template need not be concerned about revisiting data lists prepared to date.

Further details on any data protection matters are available on the APVMA’s data protection web page at http://www.apvma.gov.au/registration/data_protection.shtml.

Comments on any data protection matter can be forwarded to:

Agricultural Products

Phone: +61 2 6210 4748

Email: AgProductsCoordinator@apvma.gov.au

Veterinary Products

Phone: +61 2 6210 4726

Email: #Vet_Products_Coordinator@apvma.gov.au

By mail

Australian Pesticides and Veterinary Medicines Authority

PO Box 6182

KINGSTON ACT 2604

[Back to table of contents](#)