


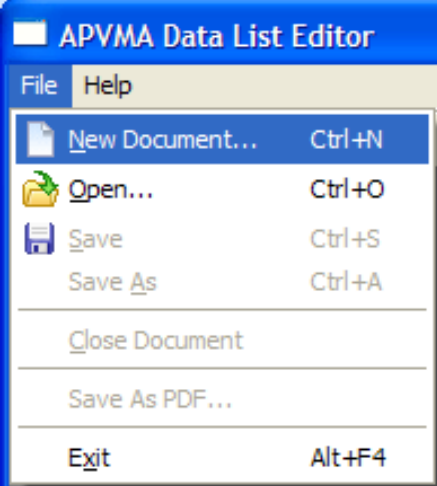


**Australian Government**  
**Australian Pesticides and  
Veterinary Medicines Authority**

## **Instructions for Using APVMA Data List Editor**

**January 2010**

## 1. Starting the data list editor

 <p data-bbox="352 636 582 667">datalisteditor.exe</p>	<h3 data-bbox="746 342 1075 376">Opening the program</h3> <p data-bbox="746 394 1289 495">Once you have downloaded the Data List Editor simply double clicking on the <b>DataListEditor.exe</b> to start the program.</p>
	<h3 data-bbox="746 792 1050 826">Creating a Data List</h3> <p data-bbox="746 844 1334 981">To create a Data List select <b>New Document</b> from the <b>File</b> menu. If you have previously begun work on a data list and wish to reopen that file select <b>Open</b> from the <b>File</b> menu.</p>

## 2. Identifying Information

APVMA Data List Editor

File Help

Applicant Details

Please email this document to: DataList@apvma.gov.au with the Product Name or Active Constituent Name in the subject heading.

Applicant's Name:

Product Name or Name of Active Constituent:

Product Number or Active Constituent Approval Number (if known):

Application Number (if known):

- In the **Applicant's Name** field, enter the Applicant name exactly as it's written on your application form.
- In the **Product Name or Name of Active Constituent** field:
  - If applying for a product (or a combined product and active constituent application), enter the name of the product exactly as it's written on your application form.
  - or**
  - If applying for an active constituent that is not combined with a product application, enter the name of the active constituent as it's written on your application form.

**Note:** DO NOT include Registered (®), Trademark (™) or Copyright (©) symbols in the name field.

- In the **Product Number or Active Constituent Number** field, enter the APVMA number if known. If not known please leave the field blank.
- In the **Application Number** field, enter the current APVMA application number for the application if known. If not known please leave the field blank.

### 3. Data List Table

The screenshot shows a web-based interface for entering data. At the top, there's a title 'Data List' and a prompt: 'Please enter the list of submitted data for the Product/Active Constituent'. Below this is a table with the following column headers: 'Ref...', 'APVM...', 'Data Type 1', 'Data Type 2', 'Author', 'Title', 'Publication', 'Date', 'Auth. Party', 'Other Party', and 'Other Det...'. To the right of the table, there are five buttons: 'Add...', 'Edit...', 'Duplicate', 'Delete', and 'Export To Excel'.

In the **Data List Table** provide the required details for every piece of information submitted with the application that meets the following criteria:

- a report (document) describing one or more tests, analyses, trials or studies (e.g. a stability trial, toxicology study, metabolism study, residue processing study, worker exposure study, ecotoxicology study, efficacy trial etc);
- a report (document) summarising information necessary to meet APVMA requirements (e.g. 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.

A guideline specifically addressing the **types of chemistry data that must be included in the Data List Table** is available from the Data Protection page of the APVMA website.

The details of the submitted information must be entered as per the instructions below. Where more than one type of information is included in the same report (e.g. multiple trials in the one report, or analytical methods included in a stability or residues trial report) the report must not be entered into the table twice and should only be identified in the table by the primary (main) Data Type and Sub-Type. Similarly if other information is attached to a report in an appendix (referred to in the document/report), separate entries for the appendices must not be included in the table. One entry of the report/document will be sufficient to identify the information.

Other information provided to the APVMA (e.g. specification sheets, certificates of analysis, MSDSs, formulation details, container specifications etc) should not be listed in the Data List table (see **Chemistry Data Guideline**).

**To begin entering information** into the Data List table **click the 'Add' button** on the right hand side of the Data List Editor template.

## 4. Details To Be Entered Into The Table

### Data Item Details

<p>Data Item Details</p> <p>Reference No</p> <input type="text"/>	<p><b>Reference number</b></p> <p>Enter your reference number as shown on the report/document provided. For published documents, you may choose to use the journal reference (e.g. volume, chapter and/or page numbers as relevant). If there is no appropriate reference number on the document/report, you must create one and add it to the document.</p> <p>Where possible it is preferable to use the volume and/or page number where the document/study can be found in the data package as the reference number. This assists the APVMA to locate the piece of information when considering the application.</p> <p>Importantly, the reference number included in the Data List Table must correspond to an obvious reference number on the actual document/report. As an identifier, the reference number should be unique to the document/report and should not be identical for all entries in the data list.</p>
<p>Data Type</p> <input type="text" value="Chemistry and Manufacture"/>	<p><b>Data Type</b></p> <p>Select data type from drop down list. This will determine the available options for the <b>Data Sub-Type</b>.</p> <p>For data that is relevant to more than one requirement, select the primary (main) data type only. <b>Do Not create two entries for one report.</b></p>
<p>Data Sub-Type</p> <input type="text" value="Active Constituent, Stability"/>	<p><b>Data Sub-Type</b></p> <p>Select data sub-type from drop down list. If you are unsure, check the Data Requirements and Guidelines in Volume 3 of the relevant Agricultural or Veterinary Manual of Guidelines and Requirements (MORAG) available from the <b>MORAG Page of the APVMA website.</b></p>

## Publication Details

<p>Publication Details</p> <p>Study Date</p> <input type="text"/>	<p><b>Study Date</b></p> <p>Enter the date as included on the report/document. If no date is included, you are required to enter the following:</p> <ul style="list-style-type: none"><li>i) If published, the date it was published; or if not published</li><li>ii) The date the preparation of the report / document was completed; or if unknown</li><li>iii) the date the report / document was received by the applicant; or if unknown</li><li>iv) the date the report / document was included in the application.</li></ul>
<p>Authors</p> <input type="text"/>	<p><b>Author(s)</b></p> <p>Enter the name of the author(s) as provided on the report/document. The sponsor of a report is not considered the author. The author is usually the person or persons responsible for the production of the report. However, in the case of privately conducted research, the company producing the report may be considered the legal author as they are responsible for its contents. If unsure please enter the name of both the person and company. If there is no author given, then use the following options in this order:</p> <ul style="list-style-type: none"><li>i) Enter the editor's name(s) with the suffix (Ed.);</li><li>ii) If no editors, enter the compilers name(s) with the suffix (Comp.); or</li><li>iii) If neither editors nor compilers, enter 'Anon'.</li></ul>
<p>Data Title</p> <input type="text"/>	<p><b>Data Title</b></p> <p>Enter the title as it appears on the report/document.</p>

Publication	<p><b>Publication</b></p> <p>If the report/document is publicly available, enter the name of the publication that it was published in. Please use the full journal name rather than the common abbreviation. If it was published on the Internet, then provide the Internet address (URL).</p> <p>If the report/document is not publicly available enter a dash (e.g. - ). The Data List Editor will automatically insert a dash whenever an authorising party other than 'public domain' is selected (see below).</p>
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## Authorising Party Details

Authorising Party Details	
Authorising Party	Reference APVMA Data No.
<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>

### Authorising Party

The 'authorising party' is the person or persons that may give consent for protected data to be used for subsequent applications. Typically the 'authorising party' will be the 'owner' of the information.

Select the authorising party type from the drop down list. Five options exist which are explained below:

#### Applicant

The applicant as identified on the data list and application form is the authorising party

#### Public Domain

The information is available in the public domain (for example it has been published and could be freely accessed by anyone).

Data protection will **not** apply to information that is available in the public domain.

#### Other Party

A party other than the applicant is the authorising party.

Where the authorising party is both the 'Applicant' and an 'Other Party', please use 'Other Party' and insert both the applicant and other party's name and address in the 'Name of Other Party' and 'Details of Other Party' Fields.

#### Prev Sub, Not Protected

The information has been previously submitted to the APVMA by the applicant but is not subject to data protection. For example the information may have been originally submitted before 1 January 2005 (when data protection began), or was submitted after 1 January 2005 but was not 'required' or not 'relied-on' by the APVMA to grant the

application with which the information was submitted. Such information may need to be supplied again to make an application for a new proposal complete (i.e. a study that contains information relevant and required for the current application).

Data protection will **not** apply to information identified as 'Prev Sub, Not Protected'.

### **Prev Sub, Protected**

The information has been previously submitted to the APVMA by the applicant and is currently subject to data protection. It may be necessary for a study to be resubmitted with a subsequent application where it contains information relevant to that application (e.g. the study reports on 2 different products). Where this applies see also APVMA Ref Data No. section below.

**Note:** It is the applicant's responsibility to ensure the correct authorising party/ies are provided in the data list. The APVMA will only accept Consent for Use from the nominated authorising party/ies. Multiple authorising parties can be nominated using "other party". If more than one Authorising Party is nominated, Consent for Use will be accepted from any of the Authorising Parties. However, there are criminal penalties for providing false information to the APVMA.

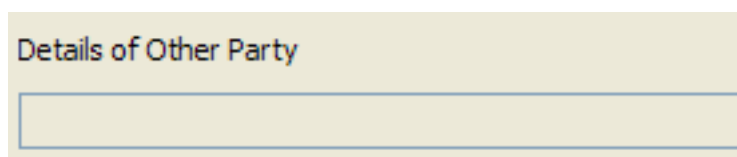
### **Name of Other Party**



When 'Other Party' is selected as the Authorising Party the 'Name of Other Party' field will become available for text entry. Enter the name of the Authorising Party.

If 'Other Party' is not selected as the Authorising Party the 'Name of Other Party' field will be grey and unavailable for text entry.

### **Details of Other Party**



When 'Other Party' is selected as the Authorising Party the 'Details of Other Party' field will become available for text entry. Enter the contact address details of the Authorising Party.

If 'Other Party' is not selected as the Authorising Party the 'Details of Other Party' field will be grey and unavailable for text entry.

### **APVMA Ref Data No.**

When 'Prev Sub, Protected' is selected as the Authorising Party (indicating that the data has been previously submitted and is already subject to data protection), the 'Reference APVMA Data No.' field will become available for text entry. You must enter the 'Reference APVMA Data No.' that the piece of information was assigned by the APVMA when it was previously submitted.

The APVMA data number will be apparent from the APVMA data list that you would have received for the application with which the information was first submitted. It may

also be obtained from the **PUBCRIS** record of the relevant registered product or approved active constituent.

If 'Prev Sub, Protected' is not selected as the Authorising Party the 'Reference APVMA Data No.' field will be grey and unavailable for text entry.

Once all the necessary fields have been completed **to accept the Data Item record click the 'OK' button** in the bottom right hand corner of the 'Add Data Item' template. To cancel the record, click the 'cancel' button.

**Note:** If a required field of the 'Add Data Item' template has not been completed correctly the 'OK' button will be grey and unavailable. Should this occur please review the entries of each field in line with the instructions above. Common oversights include:

- Blank field.
- 'Prev Sub, Protected' selected as Authorising Party but no 'Reference APVMA Data No.' included.

## 5. To Add A New Record

**Click the 'Add' button** on the right hand side of the Data List Editor template and repeat the data entry process above for the new record.

## 6. To Edit A Record

Select a data item record from the Data List Editor, Data List table by clicking on it once. Click the **Edit** button on the right hand side of the Data List Editor template. The record will open for editing.

When editing is complete click the OK button.

## 7. To Duplicate a Record

Where the data package associated with an application includes a number of similar reports or pieces of data you may find it to be more efficient to duplicate an existing record and edit the copied record as appropriate. This may save time retyping similar information (**Note:** an individual data item must only be entered into the data list once).

To duplicate a record, select the data item record from the Data List Editor, Data List table by clicking on it once. Click the **Duplicate** button on the right hand side of the Data List Editor template. The record will duplicate. Follow the instructions in Section 6 above to edit the duplicated record as appropriate for the new data item.

## 8. To Delete A Record

To delete a record, select the data item record from the Data List Editor, Data List table by clicking on it once. Click the **Delete** button on the right hand side of the Data List Editor template. The record will be deleted.

## 9. Saving the Data List

It is recommended that you save the data list regularly whilst compiling it and ensure that it is saved once completed.

To save the data list select **Save** from the **File** menu. Enter an appropriate 'file name' and select a suitable location for the file to be saved and click the **Save** button. This will only be necessary the first time the data list is saved – subsequent 'saves' will automatically be to that file and directory.

The file will be saved as an '.xml' file. This file type is acceptable to the APVMA but cannot be viewed by viewers other than the APVMA Data List Editor. To view a completed tabular version of the data list see Section 10, 'Printing the Data List' and/or Section 11, 'Exporting the Data List to Excel' below.

## 10. Printing the Data List

To print the data list select **Save as PDF** from the **File** menu. Enter an appropriate 'file name', select a suitable location for the file to be saved and click the **Save** button. The pdf file will automatically open and can be printed.

## 11. Exporting the Data List to Excel

Should you wish to view the completed data list in a spreadsheet format the Data List Editor can export the data list table to Microsoft Excel. This is obviously only possible if you have Microsoft Excel installed on your computer.

To export the data list to Excel click the **Export to Excel** button on the right hand side of the Data List Editor template. Enter an appropriate 'file name' and click the **Save** button to save the file to a suitable location (such as the directory/folder in which other related documents are located). The Excel spreadsheet will automatically open. You may wish to edit the formatting of the spreadsheet to suit your individual circumstance or purpose.

## 12. Submitting The Data List

**The APVMA will only accept the '.xml' file of the data list. Do not** submit a PDF version or a Microsoft Excel ('.xls') version. Submission of PDF or Excel files will prevent your application progressing. Such applications will be treated as incomplete until an appropriate version of the data list is received by the APVMA.

Once the data list is completed send the '.xml' file via;

i) **Email**

Attached the '.xml' file to an email. Put the product name/active constituent name and if known the APVMA product or active number and application number in the Subject heading and send to [DataList@apvma.gov.au](mailto:DataList@apvma.gov.au).  
**or**

ii) **Disk/CD**

Save to disk or CD and enclose with your application. Write the product/active constituent name and if known the APVMA product or active number and application number on the label.

**Note:** When using the Data List Editor to create your data list it is not necessary to submit a hard copy of the data list with your application.