



Australian Pesticides and Veterinary Medicines Authority

**REQUIREMENTS FOR THE
CONSTRUCTION OF ELECTRONIC
SUBMISSIONS (DOSSIERS)**

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REQUIREMENTS FOR THE CONSTRUCTION OF ELECTRONIC SUBMISSIONS

Introduction

This document sets out the APVMA's requirements for the electronic submission of application data (electronic dossiers).

It includes instructions on both the software requirements (Appendix 1) together with guidance on the format of the data should be submitted in (Appendix 2 - 4).

Background

The APVMA is committed to continuous improvement in its performance. Electronic submissions offer the potential for productivity improvements to both applicants and the APVMA.

The APVMA is also a contributor to the Organisation for Economic Co-operation and Development (OECD) that share a goal to increase performance of government regulators from member countries via harmonisation of requirements, including electronic submission of applications.

General Requirements for Data Integrity of the Electronic Dossiers

- All data contained within an electronic dossier must match the data contained in the corresponding portion of the paper application.
- No data may be presented in the electronic dossier that does not appear in the paper dossier.
- Index headings in both types of dossiers must be replicated for ease of use between the paper and the electronic dossiers.
- Pagination does not have to be identical in the paper and electronic copies of the dossiers. This should permit flexibility in the presentation of the paper dossier in an electronic format.

NOTE: you may wish to produce the paper copy directly from the electronic copy, to provide greater confidence in meeting the above requirements.

Number of Copies to be Submitted

The APVMA requires that one electronic copy and one hard copy of the dossier be initially submitted. Further copies may be required to be submitted following technical screening. Applicants will be advised if further copies are required following screening.

Virus Checking

The applicant must accept responsibility to scan the dossier for viruses. The applicant must provide the APVMA with details of the anti-virus software used (name, version, date of virus signature update file and company). This information should be included in the transmission letter.

Data Integrity

Portable Document Format (PDF) is the required file format.

Software Requirements

See Appendix 1 for details.

PDF Normal and File Size

The use of the PDF files has been shown to be efficient during evaluation. In some cases, however, there may be limitations with respect to the size of the PDF file. The following guidance is based on experience to date.

File size is not a significant issue if the file is to be page served and if there is no need to directly access the file through the Adobe Acrobat Reader. In addition, if the submission is a straight PDF-based submission, it is still possible to page serve files providing the submission is properly set up on the server being used to host the submission.

File size is an issue if the documents are not to be page served, e.g., any large study reports or assessment summaries. Desktop access to very large files can be slow. Large documents should be divided into several chapters to correspond to a title in the table of contents. It is recommended that appropriate links be created to assist with navigation and location of the elements and that each file size does not exceed approx 10 megabytes.

Australian Electronic Dossier Assembly Requirements

The following outlines the general, data and formatting regulatory requirements for the assembly of electronic dossiers being submitted to the APVMA.

As noted above one full paper copy is still required to be submitted with the electronic dossier.

Electronic dossiers must be prepared and delivered on CDs or DVDs. For ease of handling, the APVMA will request that a DVD be used where the application is too large for one CD. If a DVD is submitted the “-R” DVD format should be used. As yet, a secure, web-based delivery system has not been established, but may be a preferred option in the future.

CDs and DVDs must be labelled with the following information:

- product name (and number if available)
- active constituent name;
- company name; and
- despatch date (e.g. 03 Feb 2007).

The submission of corrected or additional data for electronic dossiers is subject to normal regulatory requirements. For each subsequent submission to the APVMA, a complete electronic dossier is required, labelled as outlined in the paragraph above with a cover letter.

Formatting

The format of the electronic submission must be as per Appendix 2 - 4.

The Table of Contents must expand out to include individual studies and summaries.

Every entry in the Table of Contents must be bookmarked, providing an immediate transfer to the correct heading or document in the dossier.

Alternatively electronic dossiers which have been formatted in accordance with an international format (i.e. OECD) may also be provided. Once again a Table of Contents must be bookmarked, providing an immediate transfer to the correct heading or document in the dossier.

To aid in the efficient use of the electronic medium, hyperlinks should also be provided within and between documents wherever an important reference is made to another study, summary, table or figure. The APVMA recognizes that the provision of hyperlinks can be a time consuming activity for applicants and applicants should use their best judgment on where the most efficiencies will be gained from hyperlinks.

APVMA Contact

For advice or clarification of technical IT issues related to preparing electronic dossiers, contact:

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Australian Pesticides and Veterinary Medicines Authority
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Email: tony.delafosse@apvma.gov.au

Specifications for Creating PDF Version of Study

Format of Original Source Document		
Feature	Specification	Comments
Software	Any word processing or desktop publishing software for IBM type or Macintosh type computer.	Use any software that can print output to a postscript printer format file (.ps) and subsequently converted to PDF format (.pdf). One purpose of using Adobe® Acrobat® is to not restrict original label creation to specific software.
Selection of Data File	Data file formats selected should permit accurate transfer of all types of data (text, tabular, graphical) to word processing or spreadsheet applications without the loss or alteration of data (e.g. font formats).	
Page size	A4	A4 is the preferred format. Please seek approval from us if you wish to submit in any other page size.
Font Size/Style - Text of study report	12 point Times New Roman.	12 point is desired, but if the PDF is created from an A-4 size source, make it fit 8.5 x 11 format. It's OK if resulting font size is not 12 point. Use of speciality fonts for math or scientific purposes is allowable provided these fonts are embedded in the resulting pdf file.
Font Size/Style - Tabular information	12 point Courier.	Courier is preferred for tabular data since it is a fixed width font. Other fixed width fonts may be suitable provided they are embedded in the resulting pdf file.

Feature	Specification	Comments
Font Type	Microsoft® True Type® or Adobe® Type 1.	Do NOT use proprietary fonts. These cannot be embedded in PDFs. Acrobat will try to use a substitute font but this may alter document format, appearance and print.
Tables	Use software “table” function rather than tabs or blank spaces to create tabular layout.	<p>Tabular text initially created in true tables and then converted to PDF readily exports to other software. Use of tabs to create the look of a table does not result in readily exportable data.</p> <p>Use clear row-column format for tabular presentation of data.</p> <p>Vertical cell merging and cell alignment can be lost during software conversions.</p>
Subscripts and Superscripts	In tables, use letters; not numerals.	Tables may be converted to other software during review process. Numerals may be converted to full size which may result in misleading numbers in tables. Therefore, use letters.

Format and Creation of PDF File		
Feature	Specification	Comments
File Format	Adobe® Portable Document Format (PDF) – Version 1.4 or higher.	
PDF File Compatibility	Adobe® Acrobat® 5.0 or higher. The APVMA currently uses adobe Adobe® Acrobat® v 7.0.	APVMA staff will use Adobe® Acrobat® 7 (full program) to perform reviews.
Software	Use any software that can create a PDF version 1.4 or higher and which can control the required settings specified in this guidance document.	
Conversion to PDF Options	The goal is to create a text PDF (smart PDF) rather than an image PDF (dumb PDF). This allows text to be interpreted as words rather than images thus allowing indexing, searching, text comparison, etc. Dumb PDF only to be used as a last option (and generally only for paper reports, where no electronic version exists).	
<ul style="list-style-type: none"> • First Choice <i>(Strongly preferred)</i> 	Convert directly from electronic source document.	This provides full indexing for text and tables.
<ul style="list-style-type: none"> • Second Choice <i>(If above not possible)</i> 	<p>Scan paper copy of study report. Process through optical character recognition (CR) software such as Adobe Acrobat Capture, ABBYY® Fine Reader®, or ScanSoft® OmniPage® Pro to create text PDF providing text extraction and indexing capabilities.</p> <p>Refer to scanning requirements below.</p>	<p>Data submitter does not have to quality assure the underlying OCR. However, more accurate text recognition in the submitted PDF file will allow for increased utility by OPP reviewers.</p> <p>Avoid overuse of cell splits and joins in tables to avoid conversion problems.</p> <p>Do not use shading in tables as it may not convert accurately.</p>

Feature	Specification	Comments
<ul style="list-style-type: none"> • Third Choice 	<p>Scan without OCR.</p> <p>This option should only be used for photographs, chromatograms, and any other graphic-based data where use of OCR is impractical.</p>	<p>This option produces a graphic-only PDF file and does not allow for required text manipulation.</p>
Scan Text and Tables	Black and white 300 dpi minimum.	The greater the scanning resolution, the more accurate will be any OCR process.
Scan Handwriting	Black and white 300 dpi minimum.	
Scan Colour Photos	<p>100-600 dpi, 24-bit RGB depending on nature and purpose of photos.</p> <p>If high resolution is critical, use 600 dpi but attach as supplemental file.</p>	<p>To avoid the creation of very large files and the need for users to scroll large photos, scan at the minimum resolution needed to achieve an accurate rendition of the original. If significant detail is required then use higher resolution.</p>
Scan Black and White Photos	<p>100-300 dpi, 8-bit gray scale.</p> <p>If high resolution is critical, use 600 dpi but attach as supplemental file.</p>	See note for colour photos above.
Scan Gels and Karyotypes	100-300 dpi, 8-bit gray scale. Do not use photographs.	
Scan Plotter Output	Capture digitally or scan at 300 dpi.	
Scan Chromatography	300 dpi.	

Feature	Specification	Comments
Adobe Acrobat Distiller Job Options	Use Agency supplied downloadable <i>job options file</i> or manually configure job options using <i>Software Settings for the Creation of PDF Files for Electronic Study Submission</i> guidance available on this web site.	This requirement applies to use of Adobe Acrobat Distiller in the creation of the study report .pdf file.
Security	Do not lock file in any way. Specifically select the following settings: Permissions - <ul style="list-style-type: none"> • Allow content copying and extraction • Comment authoring, form field fill-in or signing. Printing – <ul style="list-style-type: none"> • Fully allowed. 	Goal is to allow reuse of PDF information and printing.
File Size	No Limit.	PDF has no limit on file size. But the PC on which someone builds or reads the files can introduce constraints.
Folder and File Naming Convention – Study Reports	Use the name of the application incorporating the name of the company if possible.	The full path name must be less than 200 characters in length including all folders, subfolders and file name. All text, figures and tables related to each study should be in a single file. If supplemental files are submitted, they may be in a separate file.

Feature	Specification	Comments
Folder and File Naming Convention – Supplemental Files/Review Aids	As above.	<p>Refer to <i>supplemental/review aids</i> guidance for specific information on naming of supplemental files and review aids.</p> <p>Include all supplemental files in the same folder as the parent study report. See file-naming requirements above.</p>
Page Size	A4.	
Margins	At least 1” on all sizes.	
Page Orientation	Use source document orientation.	
Page Numbering	Same as source document.	
Font Embedding	Embedded all fonts except for Base 14 fonts.	<p>Goal is to embed all fonts used in document to ensure correct formatting, appearance and printing of document. It is recommended that the PDF be created on the same computer on which the original source document was created so the same non-proprietary fonts are available. Using the “when embedding fails – cancel job” option will make it obvious when font problems exist.</p> <p><u>Do NOT use proprietary fonts.</u> These cannot be embedded in PDFs. Acrobat will try to use a substitute font but this may alter document format, appearance and print.</p>

Feature	Specification	Comments
Electronic Signatures	Not implemented at present.	
Bookmarks – Submission Transmittal Letter	Create bookmark for each item listed in the transmittal letter.	This can include all elements of an application (Application form, label, studies, etc).
Bookmarks – Study Table of Contents	Create bookmark for each item in table of contents of study report document.	<i>To be provided.</i>
Bookmark Hierarchy	Limit to no more than four levels in either full submission or within a single study.	Consensus is that people get ‘lost’ when there are more than four levels.
Hypertext Linking	Yes. Use <i>Inherit Zoom</i> magnification setting.	
Link Supporting Information	Yes, when not on the same page. Link tables and appendices to reference in text.	
Link Style	Blue text.	If printed, paper version is being used, the blue won’t appear. Underlining (in addition to blue text) takes many steps. Since linking should be obvious from the context in which it appears, no special markings need be done for paper version.
Indexing	Not required at this time.	This includes both the Document Property > Summary Data of the PDF and Indexing using the Adobe® Acrobat® Cataloguing capability.
Open Dialog Box	Use <i>Bookmarks & Page</i> . If no bookmarks, then <i>Page only</i> .	
Electronic Supplemental Files/Review Aids	See Supplemental Files/Review Aids guidance documents.	

Feature	Specification	Comments
Chemical Structure Information	Submit as Rdfiles, Sdfiles or Molfiles.	Submit mechanistic and metabolic pathway data when either a new chemical submission or additional data on existing chemicals. Use any software capable of creating the appropriate file type. Attach file(s) to study PDF and bookmark/link accordingly.

Submission of PDF Study		
Feature	Specification	Comments
Submission Medium	Compact Disk (CD-ROM).	Disk must be compatible with Windows 95 or higher. Do not use floppy disks.
Labelling of CD and Jewel Case	Registrant, Active Ingredient, brief description of application on both.	Provide only one submission per CD; however, multiple CDs may be used for one submission if required.
Transmittal Document	Locate the transmittal document PDF file in the root folder of the CD-ROM. Name this file " TRANSMITTAL.PDF ".	
How to Submit	See guidance document <i>Preparation and In-Processing of Studies Submitted in PDF</i> .	
Where to Submit	Send via courier service to APVMA physical location: The APVMA PO Box E240 KINGSTON ACT 2604	

**APPLICATION DOSSIER FORMAT FOR
PESTICIDES SUBMISSIONS FORMATS**

APVMA FORMAT

OECD FORMAT

SUMMARY OF MORAG DATA REQUIREMENTS

SUMMARY OF OECD DATA REQUIREMENTS

1. PROCEDURES FOR MAKING AN APPLICATION

2. CHEMISTRY AND MANUFACTURE

3. TOXICOLOGY

4. METABOLISM AND KINETICS

5A. RESIDUES

5B. RESIDUES & TRADE

6. OCCUPATIONAL HEALTH AND SAFETY

7A. ENVIRONMENTAL CHEMISTRY AND FATE

8. EFFICACY AND CROP SAFETY

9. OTHER TRADE ASPECTS

10. SPECIAL DATA

APPLICATION DOSSIER FORMAT FOR
VETERINARY PHARMACEUTICAL SUBMISSIONS

APVMA FORMAT REQUIREMENTS

1. OVERVIEW

2. CHEMISTRY AND MANUFACTURE

3. TOXICOLOGY

4. METABOLISM AND KINETICS

5A. RESIDUES

5B. RESIDUES & TRADE

6. OCCUPATIONAL HEALTH AND SAFETY

7. ENVIRONMENTAL CHEMISTRY AND FATE

8. EFFICACY AND TARGET ANIMAL SAFETY

9. OTHER TRADE ASPECTS

10. SPECIAL DATA

APPLICATION DOSSIER FORMAT FOR
VETERINARY IMMUNOBIOLOGICALS SUBMISSIONS

APVMA FORMAT REQUIREMENTS

PART I. SUMMARY OF DOSSIER

**PART II. CHEMICAL, PHARMACEUTICAL AND
BIOLOGICAL DOCUMENTATION**

**PART III. SAFETY AND EFFICACY
DOCUMENTATION**

PART IV. BIBLIOGRAPHIC REFERENCES