Ministry for Primary Industries
Manatū Ahu Matua

E-Files for ACVM Applications

ACVM Guideline

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1 Introduction

This guideline is to be followed by all applicants when submitting their application documents and supporting information in electronic format. It specifies the basic parameters required for an acceptable electronic submission to be known as **ACVM E-Files**. A well-constructed, named and indexed submission expedites the screening and review process, and reduces assessment time and associated fees.

Application files that do not comply with this guidance may not be accepted at screening.

2 Scope

This guideline covers information submitted for all types of applications made under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, such as applications for Registration, Provisional Registration, Deviation requests, Special Circumstances approvals, Operating Plan approvals, and Class Determinations.

3 Methods used for submission of E-Files

MPI requires all application documentation and supporting information to be provided electronically. The following information transmission methods are listed in order of MPI's preference.

3.1 ShareFile

ShareFile is an on-line tool that enables secure file-sharing with MPI. ShareFile is MPI's preferred method of receiving confidential information.

ShareFile keeps documents secure on an MPI server. Files uploaded to ShareFile are only stored for 30 days, after which they are automatically deleted. There is no maximum file size, but some file types (such as executables) are not allowed. Zip files[1] can be uploaded in ShareFile.

ShareFile can help you send any file of any size (unlimited) instead of sending a regular attachment by email. ShareFile allows MPI staff to send links that allow you to upload your submission files. Files are then downloaded from ShareFile by MPI staff. You will be notified by email when the link has been sent, and again when your submission files have been downloaded by MPI staff. Should you not receive an email notification after 30 days of uploading your files, contact either your Operations Adviser or approvals@mpi.govt.nz

You must request a ShareFile link to upload your submission files. You can request a link by emailing either your Operations Adviser or approvals@mpi.govt.nz
It is helpful to provide your full contact details and a brief description of your application when you request the link.

3.2 Email

Email is a less secure method of sending confidential information compared to ShareFile. Should you choose to use email, you do so at your own risk.

MPI's email system has an 8 MB limit. Therefore, if your submission files exceed this limit, you must use either ShareFile (preferably) or portable media.

Do not send your application documents spread over several emails.

You may email your application to either your Operations Adviser or to approvals@mpi.govt.nz .

3.3 Media

Electronic files may be submitted electronically using portable media such as CD, DVD, or USB memory sticks. Each CD, DVD or USB memory stick containing an e-submission should include at a minimum the following label information:

- name of the product(s);
- registration number (if known in advance by the applicant);
- name of applicant;
- If there is room on the label, include the type of application (e.g. B2 application) or request being made (e.g. class determination).

Print this information directly onto discs because hand-written or self-adhesive labels may compromise the discs or peel-off in time. For USB memory sticks, self-adhesive labels are acceptable.

If more than one media component is needed, the application should be split at a logical point within the documentation so that the integrity of the information is maintained. If possible, individual dossier parts (Part 1, Part 2 etc.) should be kept together and not be split over multiple media components.

[1] This is a file that contains one or more files that have been compressed into the ZIP format. Zipped files take up less storage space and can be transferred to other computers more quickly than uncompressed files.

For submission of multiple product applications, provide files zipped by trade name product to enable MPI staff to clearly identify each product application.

Media will not be returned to the applicant unless specifically requested with provision of a self-addressed pre-paid courier bag. Media that is not returned to the applicant will be securely destroyed by MPI.

4 Language

All documents must be submitted in English.

5 File format and source

Submit all documentation using file formats that facilitate both reviews on screen and paper while retaining a similar format. If documents have graphs etc., use of a colour file format is preferred.

The portable document format (PDF) is a format that supports the described features. The PDF format used for an application should be legible with Acrobat Reader version 5.0 or higher. Files should be compatible with PDF 1.4 (or as updated by the ISO norm). No PDF documents should be in version PDF 1.3 or earlier. Files should be searchable.

To ensure that PDF files can be accessed efficiently, PDF files should preferably be no larger than 100 MB. If the PDF file size is larger than 100MB, the file should be split. Splitting should be done at a sensible point to facilitate the review (i.e. do not split in the middle of a paragraph but rather between the text and the annexes for instance). The files should be named as “1ofx”, “2ofx”.
Example: P01234-Efficacykiwifruit-1of2.pdf

Word document format is required for some application documents, such as the Identification of Confidential Information for the Purpose of Data Protection form.

6 Requirements for creating PDF files for electronic submission

6.1 Electronic source documents

To allow functionality such as text searching, copying and pasting into editable formats, PDF documents should be preferably created (rendered) directly from their electronic source documents.

Electronic signatures in application documents

MPI requires application documents to be electronically signed, in accordance with section 22 of the Electronic Transactions Act 2002.

Fonts for electronic source documents

Font point sizes should ensure on-screen readability (for example, at least 11-12 for normal text, 9-10 for tables and 8-10 for footnotes). The recommended font colour is black.

Page format and numbering for electronic source documents

The print area for pages should fit on ISO 216:2007 A4 sheet of paper with sufficient margins with the exception of the mock-ups for packaging components, which may require other formats. Pages should be

properly oriented to reduce the time spent having to rotate pages. Pages within a file should be numbered.

6.2 Paper source documents

MPI prefers not to receive paper source documents. PDF documents submitted as scans of paper documents should be scanned at resolutions that will ensure the pages are legible both on the computer screen and when printed. Normally 300 dpi gives good results without compromising file size for text; higher resolution may be required for graphics.

Ensure that the quality of the renditions is adequate for regulatory review, and that the content is searchable. Ensure scanned pages are saved as a single PDF document, not submitted as multiple single page PDF files.

7 ACVM E-File naming convention

7.1 General

- File names must be in English, and should be **descriptive and unambiguous**, especially if more than one PDF is included in a particular section. We encourage you to use any information that may help identify the contents of the file in the file name.

- **Do not** use file names that do not clearly identify the content/purpose of the file; e.g. codes, numerical strings.

- Avoid excessively long file names. The length of a path including file name and extension should not exceed 180 characters.

- Dates are required for PDS and Label file names. Use the Date convention YYYYMMDD as numerals, e.g. 20170919 is the 19th September 2017. The date must precede the rest of the file name, e.g. 20170919 P001234 PDS.

- Use capital letters or spaces to separate words. **Do not** use underscores.

- Only use alphanumeric characters and commas or hyphens.

- Because 'special' characters impede search capability in the MPI system, the file name cannot contain the following characters:

/	\	*	&	:	?	(	)	<	>	{	}

7.2 Applications for new registration

If the registration number is not known use: 'TradeName Descriptor'. The TradeName Descriptor is the full product Trade Name.

Examples: AA DOGWORMER Letter of Authorisation NZ Agent
20170919 AA DOGWORMER PDS
20170919 AA DOGWORMER Label clean
20170919 AA DOGWORMER Label tracked changes
AA DOGWORMER Application form

AA DOGWORMER Identification of Confidential Information
AA DOGWORMER Chemistry and Manufacturing 1of2
AA DOGWORMER Chemistry and Manufacturing 2of2
AA DOGWORMER Efficacy Study SR54923-01
AA DOGWORMER Target Animal Safety Study SR2201-01

7.3 Applications for varying a registration

If the registration number is known use: 'Regnumber Descriptor'. The registration number descriptor should be expressed as six digits.

Examples: P001234 Covering Letter
20170919 P001234 PDS
20170919 P001234 Label tracked changes
20170919 P001234 Label clean
P001234 Application form
P001234 Identification of Confidential Information form
P001234 Residue Study 30245
P001234 CoAs
P001234 Batch Analyses
P001234 Stability study

For any additional information and supporting data provided during appraisal of the application, please use the same naming convention e.g.: 'Tradename descriptor' or 'Regnumber descriptor'.

7.4 Deviations from information requirements

- If the deviation number is known use: 'DVnumber Descriptor'
  Example: DV5 Covering Letter
- If the Deviation number is not known use: DV TradeName Descriptor
  Example: DV Acme Cat Wormer Covering Letter

7.5 Class determinations

- Use: 'CD TradeName descriptor'
  Example: CD Bobs Surfactant Covering Letter

7.6 Special circumstances

- Use: 'SC TradeName descriptor'
  Example: SC Johne's Vaccine Covering Letter

7.7 Biosecurity clearance applications

Identify these documents using the same file naming convention, i.e. 'TradeName Biosecurity descriptor' or (if known) 'Regnumber Biosecurity descriptor'.

8 Structuring E-Files for submission

Your e-submission must be structured as follows:

8.1 Administrative files

All administrative files must be presented as separate files (not zipped). These include:

- Application forms
- Product Data Sheet
  Note: if an updated PDS is provided after the application has been submitted, name the file correctly and update the date in the document footer.
- Label content (clean copy and tracked changes copy if changes are requested)
  Note: if an updated label is provided after the application has been submitted, name the file correctly and update the date in the document footer.
- Identification of Confidential Information for the Purpose of Data Protection form. This **must be** supplied as a word document.
  Note: If an updated form after the application has been submitted, keep the file name the same and update the date in the document footer.
- Letters of consent (e.g. for use of protected confidential information; authorising an agent; authorising transfer of a registration)
- Data Assessment Reports
- Deviation opinion letters issued by MPI
- EPA approval documentation (if relevant)
- Current GMP documentation for product formulators/manufacturing sites (for veterinary medicine and vertebrate toxic agent products).
- Expert opinions. If an expert opinion covers the entirety of the application, this can sit outside the dossier section zip files with the other administrative documents. If an expert opinion is specific to a part of an application (e.g. efficacy) then it should sit within that dossier section zip file.

8.2 Technical documentation – Dossier section zip files

All technical information (including information supporting deviation requests, technical arguments, expert opinions and study data) must be presented with all the associated individual files zipped together according to the relevant dossier sections (e.g. Chemistry and Manufacturing, Residues etc.), and named as below.

If the Registration Number is not known, use the product's full Trade Name.

<u>For Agricultural Chemicals, name dossier section zip files</u>:

- RegNumber Descriptor Chemistry and Manufacturing
- RegNumber Descriptor Residues
- RegNumber Descriptor Efficacy and Crop Safety
- RegNumber Descriptor Toxicology

<u>For Veterinary Medicines, name dossier section zip files:</u>

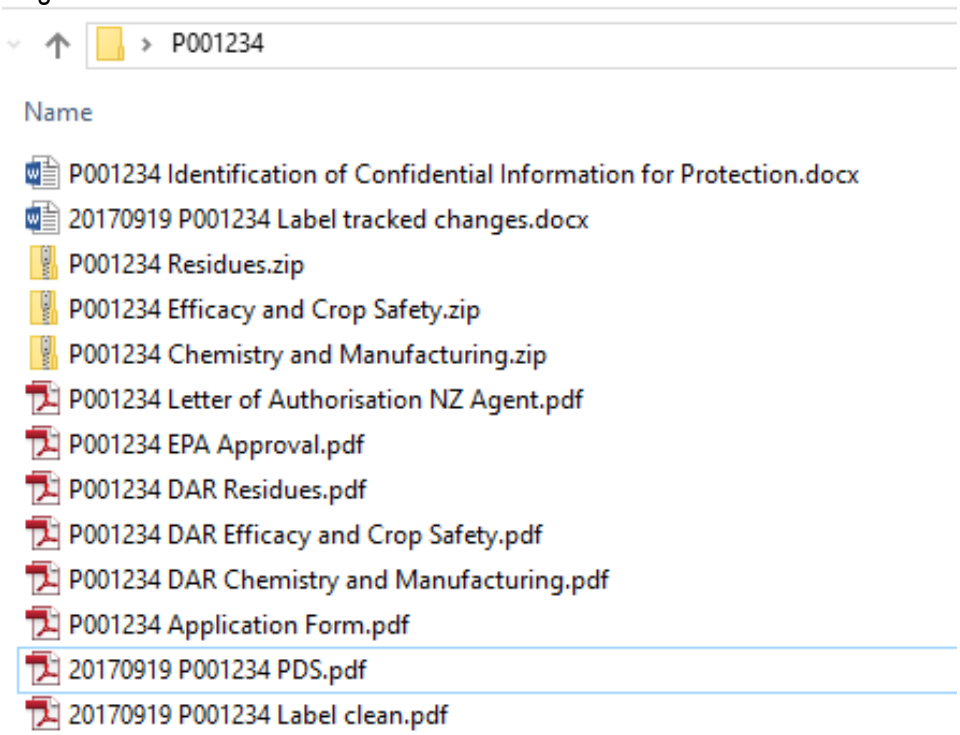
- RegNumber Descriptor Chemistry and Manufacturing
- RegNumber Descriptor Residues
- RegNumber Descriptor Efficacy
- RegNumber Descriptor Target Animal Safety
- RegNumber Descriptor Toxicology
- RegNumber Descriptor Antimicrobial Resistance

<u>For Vertebrate Toxic Agents, name dossier section zip files:</u>

- RegNumber Descriptor Chemistry and Manufacturing

- RegNumber Descriptor Residues
- RegNumber Descriptor Efficacy
- RegNumber Descriptor Target Animal Welfare

Example: An agricultural chemical submission



IMPORTANT: Do not use folders in zip files. Zip files must only contain individual files.
If possible, present each dossier section as one zip file. When not possible, name the zip files accordingly (e.g. P001234 Efficacy and Crop Safety 1of2; and P001234 Efficacy and Crop Safety 2of2).

8.3 Technical documentation - Structure of individual files in dossier sections

- The number of files should reflect the size of the dossier.
- Files may be in PDF, Word document, Excel, or image (jpeg, png, gif) formats.
- Individual files should not exceed 100 MB.
- Individual files should be named according to the ACVM E-File naming convention.
- Study reports and/or other literature will usually accompany the application. These can be provided as individual PDF files or as a single PDF containing a number of studies. **In general, providing each study as a single PDF file is preferred.** If a single PDF containing multiple studies is provided, the PDF **must** be indexed (table of contents or index page) or bookmarked (see example on page 9).
- PDF files that are required in more than one section of the dossier should be submitted in each section required. Hyperlinks between files do not transfer with uploading of files into the MPI system.
- If more than one PDF file is provided in any section, discrete studies or reports should not be split between PDF files unless necessary. If splitting is necessary, it should be done at a sensible point to facilitate the review (i.e. do not split in the middle of a paragraph but rather between the text and the annexes for instance). The files should be named as “1ofx”, “2ofx”

Example: P001234-Efficacykiwifruit-1of2.pdf

- The contents of the dossier section zip files should be organised in a logical and easy to navigate way, preferably that reflects the ACVM information guidelines, such as:

→ Administration documents (application forms, DARs, Label, PDS etc.) **NOT ZIPPED**

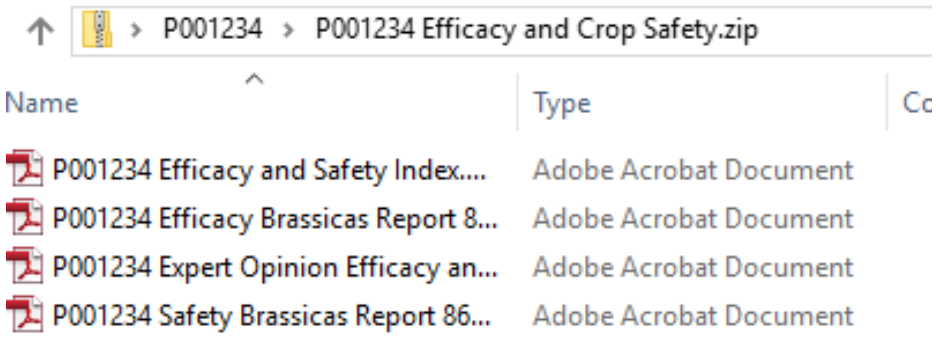
→ Chemistry and Manufacturing zip file; containing:
- → Active Ingredient file
  - → Batch analysis file
- → Formulated Product file
  - →Batch analysis file…. Etc.

→ Efficacy zip file; containing:
- → Efficacy study 1file
  - → Raw data file
- → Supporting information file…. Etc.

→ Target Animal Safety zip file; containing:
- → Expert opinion file
- → DV 989 file
  - → DV supporting information file
- → Safety study 1 file
  - → Raw data file
- → Safety study 2 file
  - → Raw data file …. Etc.

→ Residues zip file; containing:
- → Residue study 1 file
  - → Raw data file
- → Residue study 2 file
  - → Raw data file…. Etc.

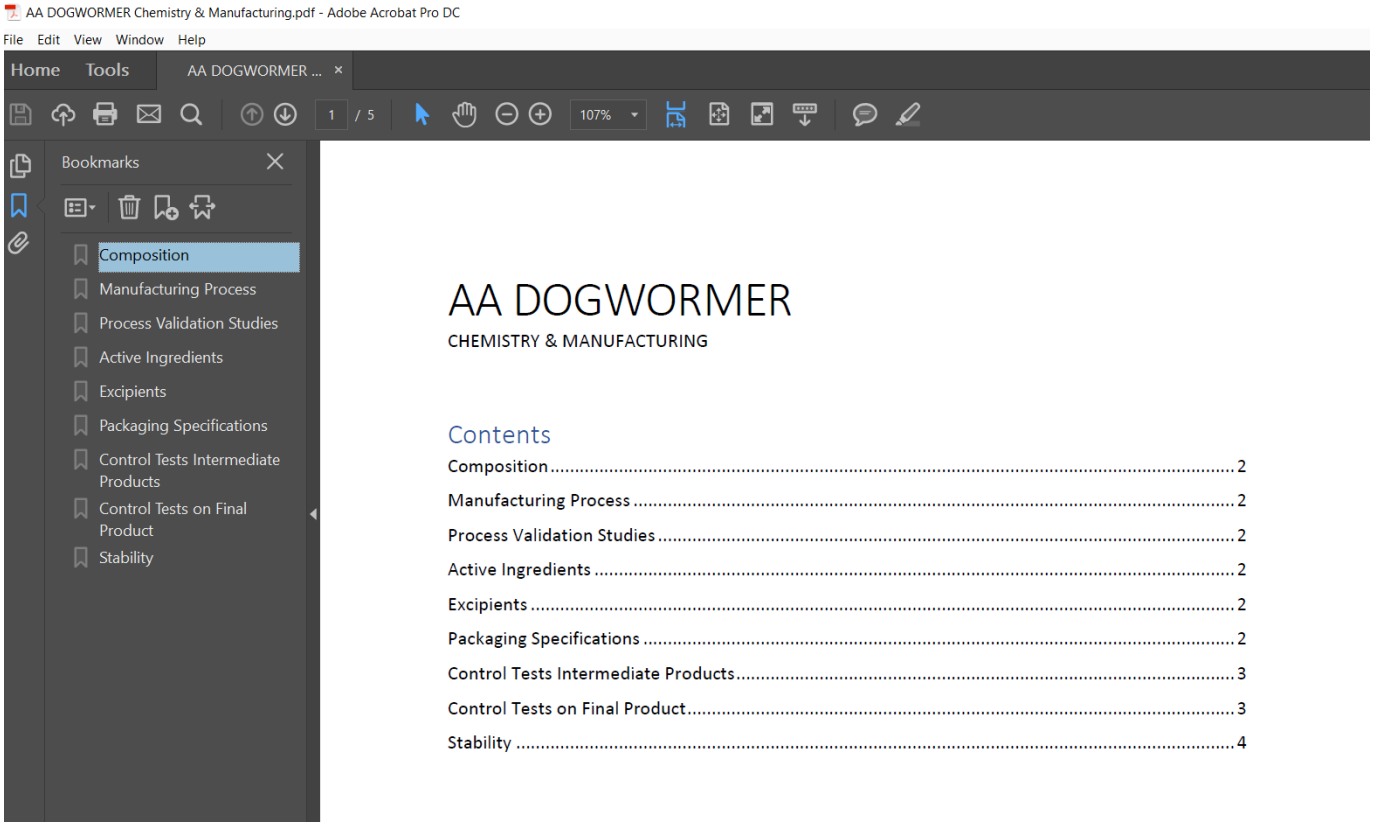
Example: The Efficacy and Crop Safety dossier section Zip File containing individual files:



- If more than one piece of information is presented in a single PDF file (e.g. manufacturing process, release and expiry specifications and stability study present in a single chemistry and

manufacturing PDF), the PDF file must have all the contents either indexed (table of contents/index page) or bookmarked to enable navigation of the file and ease of review.

Example of bookmarks in a PDF:



9 Submission of confidential E-Files by third parties

If a third party is submitting information in support of an application directly to MPI, the files must be named according to the same file naming convention using the **NZ trade name**, and an appropriate descriptor of the information contained within the file. This enables the information to be accurately identified upon receipt at MPI.

It is the responsibility of the applicant to advise the third party of this requirement.

For multiple PDF files, i.e. if a Chemistry and Manufacturing dossier is being submitted directly in confidence to MPI, the zip file must be named using the NZ trade name of the product, and the appropriate dossier section:
Example: Smith Glyphosate Chemistry and Manufacturing