

Part 1
Application Overview

Contents

1. PURPOSE OF THE APPLICATION OVERVIEW..... 1

2. REQUIREMENTS AND GUIDELINES..... 1

 2.1. Length..... 1

 2.2. Presentation 1

 2.3. Content 2

 2.4. Draft label 5

 2.5. References 5

 2.6. Attachments..... 6

Revision history..... 6

This page is blank for
double-sided printing

1. PURPOSE OF THE APPLICATION OVERVIEW

Part 1 of an application dossier includes the combined Application Form and Overview. The purpose of the Overview section of the combined document is to provide a brief outline of the application. The Overview may contain other general information on the product, and a summary of all data in the application. The Overview is intended to lead reviewers through a submission.

An Application Overview must be included with the majority of application categories, but not all. Detailed information is provided in the specific category chapters in Volume 2: Category requirements and guidelines.

Some parts of the Overview may not be applicable for new products based on existing active constituents and for variations to existing products. If an applicant considers that the APVMA should not require certain information, the applicant must make a statement to that effect under the appropriate heading, together with the reasons (scientific argument) for not including the information. The APVMA will consider each such request on its merits.

Information provided in the Overview need not be repeated elsewhere in a submission. If the requirements of one of the application categories state that information or data should be presented in another part of the same submission, this may be simply done by reference to the information provided in the Overview.

If a future application is made to vary the registration of a product, applicants must complete an Application Form and Overview which gives full details of all variations. However, for product details which remain unchanged, applicants may refer to the date of the original application for registration of the product or the date when the APVMA last approved other variations.

2. REQUIREMENTS AND GUIDELINES

2.1. Length

The length of the Application Overview will vary depending on the nature and category of the application. As a guide, the Overview should be less than 20 pages.

2.2. Presentation

All pages of the application must be numbered. Separators with tabs may be used to identify attachments. The document must be unbound.

If an application contains data in a format that is inconsistent with APVMA data Parts 2–10 (eg data submitted to an overseas authority), a table of contents must be provided for each data part, cross-referencing with APVMA data Parts 2–10. The cross-reference table of contents must be included as an attachment to the Application Overview.

Further details on how to format data for submission of an application may be found in '*Procedures for making an application*' in Volume 1.

2.3. Content

The following headings are sub-parts of Part 1. Applicants must retain the sub-part numbering system because the heading numbers correlate to the number of the other data Parts.

1.1. Introductory information

(a) Completed Application Form

See the explanatory notes provided with the Application Form.

(b) Executive summary of the application

The Executive summary of the application should include the reasons for the application. For a new product this will state whether the product contains a new active constituent and include a detailed scientific argument for registration of the product and outlining the importance, prevalence and (if necessary) the regional distribution of the disease/pest/problem the product is intended to control, plus the economic and/or technical advantages of the product.

For variations to a registered product, the Executive Summary should specify all proposed changes.

(c) Reference product/s

Indicate the name and product number of any reference products. If there is no reference product, write 'Not Applicable'.

(d) Quantity likely to be used in first 2 years of registration

An estimate of the quantity of active constituent expected to be manufactured or imported during the first 2 years must be provided.

The basis for the estimate should be provided together with an indication of whether the product is expected to replace existing registered product in the marketplace. If the application is for variation to a registered product, write 'Not Applicable' in this section.

(e) Registration status overseas for this and related formulations

The application must state whether there are any known current or previous applications or approvals in other countries for products containing the same active constituent. Where the product has previously been the subject of evaluation, full details of the outcome must be provided. If any data in the submission have been rejected by an overseas or Australian regulatory body, the applicant must identify this and submit scientific argument against the rejection.

The application must provide full details of the overseas-approved use pattern (host species, claims, directions for use and withholding periods), including any restrictions of use.

Where available, overseas evaluation reports should be provided in the relevant Parts of the submission.

(f) **Related submissions before the APVMA**

The applicant must provide the status of any previous or current applications the applicant has made for any other product containing this active constituent.

(g) **Data contradicting or changing conclusions from previous applications**

Indicate whether the data or conclusions presented in the current application contradict data or conclusions in previous applications, including a full explanation of how the new data can be justified.

1.2. Chemistry and manufacture

Declaration whether a separate Part 2 is included.

If a separate Part 2 is not included, scientific argument for not submitting data must be provided.

Briefly summarise any stability studies that have been submitted in Part 2.

Insert/attach batch release and expiry specifications for the product.

1.3. Toxicology

Declaration whether a separate Part 3 is included.

If a separate Part 3 is not included, scientific argument for not submitting data must be provided.

Briefly summarise any toxicology studies that have been submitted in Part 3.

1.4. Metabolism & kinetics

Declaration whether a separate Part 4 is included.

If a separate Part 4 is not included, scientific argument for not submitting data must be provided.

Briefly summarise any metabolism and kinetics studies that have been submitted in Part 4.

1.5. Residues and trade considerations (food crops only)

Declaration whether a separate Part 5 is included.

If a separate Part 5 is not included, scientific argument for not submitting data must be provided.

If a Part 5 dossier has been provided, insert here the summary section of the residues studies (Part 5A) and any trade data (Part 5B).

1.6. Occupational health and safety

Declaration whether a separate Part 6 is included.

If a separate Part 6 is not included, scientific argument for not submitting data must be provided.

Briefly summarise any occupational health and safety studies that have been submitted in Part 6.

1.7. Environmental safety

Declaration whether a separate Part 7 is included.

If a separate Part 7 is not included, scientific argument for not submitting data must be provided.

1.8. Target crop efficacy and safety

Declaration whether a separate Part 8 is included.

If a separate Part 8 is not included, scientific argument for not submitting data must be provided.

If a Part 8 dossier has been provided, insert here the summary section of the efficacy and safety studies.

1.9. Other trade aspects

This Part must include a summary of the data/argument that use of the product will not unduly prejudice trade for concerns other than food residues concerns. Other types of concerns are:

- residues in fibre crops
- disease outbreaks from products containing live organisms
- interference with disease diagnostic programs from vaccine products, and
- market resistance of overseas consumers, for example with GMOs.

Declaration whether a separate Part 9 is included.

If a separate Part 9 is not included, scientific argument for not submitting data must be provided.

1.10. Special data

Declaration whether a separate Part 10 is included.

If a separate Part 10 is not included, scientific argument for not submitting data must be provided.

If relevant, briefly summarise any data relating to antibiotic resistance risks to humans associated with use of the product, which have been submitted in Part 10.

Where a product's registration by the APVMA is contingent upon advice from the Office of the Gene Technology Regulator (OGTR), or an import permit is required to be issued by the Australian Quarantine and Inspection Service (AQIS), the relevant documentation must be referred to in Part 1.10 and a copy attached.

2.4. Draft label

All components of the proposed product label (primary pack, immediate container, leaflet) must be included in the Application Overview.

The claims to be made on the label are the only claims which may be used in sales promotion. It is therefore in the applicant's interest to make sure that claims are clearly stated and substantiated by data/argument in the detailed application.

Applicants should consult Volume 5 for specific information on labelling and the label approval process.

2.5. References

The common name for the pest, weed or disease, based on the appropriate current references listed below should be used:

Insects: Australian Insect Common Names www.ento.csiro.au/aicn

CSIRO Handbook of Australian Insect names 1993

Weeds: Shepherd RCH, RG Richardson & FJ Richardson (2001) Plants of Importance to Australia, A Checklist.

Lazarides M, K Cowley & P Hohnen (1997) CSIRO Handbook of Australian Weeds.

Lazarides M & B Hince (1993) Handbook of Economic Plants of Australia, CSIRO.

Diseases: No current national reference exists, however checklists of recorded plant diseases are available from State agricultural authorities. Other useful references include current editions of:

Ornamental Plants. Pests, Diseases and Disorders. DPI Queensland. ISBN 0 7242 5967 8.

Cereal Leaf and Stem Diseases. GRDC. ISBN 0 642 18241 8.

Diseases of Vegetable Crops. DPI Queensland. ISBN 0 7242 5372 6.

Diseases of Fruit Crops. DPI Queensland. ISBN 0 7242 3981 2.

2.6. Attachments

Attachments, where applicable, should be identified and attached to the Application Overview. Attachments may include:

- draft copies of the product label
- copy of the current approved label with changes identified (for variations)
- data protection: Data List and Consent-for-use letter
- letter of authority for an approved person
- GMP certificates/documentation
- AQIS import permits
- OGTR approval documents
- table of contents for each data part (for data in overseas format) cross-referencing with APVMA Data Parts 2–10.

Revision history

Revision date	Description of revision
1 July 2005	First edition
1 October 2005	Second edition <ul style="list-style-type: none"> • paragraph 1.7: minor edit to refer to VICH Phase I • paragraph 2.2: revised presentation of application overview, removed requirement for covering page • added paragraph 2.4 describing attachments • paragraph 3: subparagraphs renumbered.
1 April 2006	Third edition <ul style="list-style-type: none"> • paragraph 2.3 [1.5]: changed instruction to include summary section of Part 5A and Part 5B under subpart 1.5 • paragraph 2.3 [1.8]: changed instruction to include summary section of Part 8 under subpart 1.8 • paragraph 2.3 [1.10]: added reference to antibiotic resistance • paragraph 3 [1.1e]: clarified text concerning overseas applications.
1 July 2007	Fourth edition <ul style="list-style-type: none"> • change to presentation and minor text edits.