

REVISIONS TO VET MORAG DOCUMENTS IN EDITION 4

MORAG DOCUMENT	REVISIONS
MORAG website front page	<ul style="list-style-type: none"> complete redesign
Volume 1	
Introduction to MORAG	<ul style="list-style-type: none"> minor text edits
Legal background to the National Registration Scheme	<ul style="list-style-type: none"> minor text edits
Procedures for making an application	<ul style="list-style-type: none"> edit 'binding' section to say that plastic arnos-type binders are not suitable revise section 3 (approved persons) for clarity add new paragraph 4.6 re electronic submissions add new paragraph 4.7 re EARS add new paragraph 5.4 re screening timeframe general text edits.
Legislative Instruments	<ul style="list-style-type: none"> no change
Volume 2	
How to use Volume 2	<ul style="list-style-type: none"> minor text edits.
Category 1 Registration of a new product containing a new active constituent	<ul style="list-style-type: none"> minor text edits.
Category 2 Registration of a new product containing a new active constituent: modular assessment	<ul style="list-style-type: none"> paragraph 2.3: edit re label requirements paragraph 2.6: edit re provision of data lists for chemistry data paragraph 3.1: edit to give greater clarity to secondary applications and delete statement that products which contain more than one new active constituent will require more than one application minor text edits.
Category 3 Registration of a new product containing an active constituent contained in no other product	<ul style="list-style-type: none"> minor text edits

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Category 4 Not relevant to veterinary applications	<ul style="list-style-type: none"> no changes.
Category 5 Registration of a product which is similar to a registered product	<ul style="list-style-type: none"> paragraph 2.3: revised label requirements paragraph 2.5: removed inaccurate reference to Module 12. Edited to state that applicants must provide a Data List for chemistry and manufacture data minor text edits.
Category 6 Registration of a product which is closely similar to a registered product	<ul style="list-style-type: none"> paragraph 2.3: revised label requirements paragraph 2.5: edited to state that applicants must provide a Data List for chemistry and manufacture data minor text edits.
Category 7 Registration of a product which is closely similar to a registered product: chemistry assessment not required	<ul style="list-style-type: none"> paragraph 1.2: refer to pioneer reference product paragraph 2.2: new paragraph added to state that data are not required paragraph 2.3: revised label requirements minor text edits.
Category 8 Repack of a registered product	<ul style="list-style-type: none"> add new paragraph 2.2.1 re EARS paragraph 2.3: additional text to say that the formulator's declaration is also taken to be consent for use of protected data; edit to say that a 'consent for use' letter is not required. paragraph 2.5: revised label requirements paragraph 2.8: correction to wording add paragraph 2.8.1 to say that formulators who do not consent to the use of protected data, should say so in the formulator's declaration minor text edits.
Category 9 Listed registration	<ul style="list-style-type: none"> removed the requirement to provide a draft label in paragraph 2.2 minor text edits.
Category 10 Not relevant to veterinary applications Not relevant to veterinary applications	<ul style="list-style-type: none"> paragraph 2.3: revised label requirements insert new paragraph 2.6 re public consultation edit paragraph 2.7 (previously paragraph 2.6) re provision of data lists for chemistry data minor text edits.
Category 11 Not relevant to veterinary applications	<ul style="list-style-type: none"> no changes.

MORAG DOCUMENT	REVISIONS
<p>Category 12 Minor variation where no technical data are required</p>	<ul style="list-style-type: none"> • paragraph 2.2: revised label requirements • add new paragraph 2.1.1 re EARS • add new paragraph 2.3.1 re an identical change to multiple products • paragraph 3.3: edit to state that variations other than those described in the text should be made under Category 14 • paragraph 4: edit to state that Category 12 cannot be used to retrospectively legitimise previous product variations • paragraph 4: edit to better define ‘minor variation’ to non-active constituents • minor text edits.
<p>Category 13 Variation required by the APVMA</p>	<ul style="list-style-type: none"> • add new paragraph 2.1 to clarify that an application form is required • add new paragraph 2.2.1 re EARS • paragraph 2.2: revised label requirements • minor text edits.
<p>Category 14 Variation: modular assessment</p>	<ul style="list-style-type: none"> • paragraph 2.3: revised label requirements • new paragraph 2.4.1 and 2.4.2 re the fee for identical variations to multiple products • paragraph 2.7: edit to explain that a data list and Module 12 are now required for applications involving chemistry assessment only • add paragraph 4.5.1 to enable variations to active constituents to be made under Category 14, and edit other text for consistency • paragraph 4.5.2: edit to refer to Category 12 for certain variations to non-active constituents • paragraph 4.5.7: edit to further define variation to product specifications • minor text edits.
<p>Category 15 Approval of a new active constituent</p>	<ul style="list-style-type: none"> • add new paragraph 1.1 to say that applications under Category 15 are rarely used for veterinary medicines • minor text edits.
<p>Category 16 Approval of a new active constituent: limited toxicology assessment</p>	<ul style="list-style-type: none"> • add new paragraph 1.1 to say that applications under Category 16 are rarely used for veterinary medicines • minor text edits.
<p>Category 17 Approval of a new active constituent: toxicology assessment not required</p>	<ul style="list-style-type: none"> • edit introduction to say that applications under Category 17 are generally not relevant to veterinary medicines • paragraph 1.1 amended relating to ectoparasiticide active constituents.

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Category 18 Variation to an active constituent	<ul style="list-style-type: none"> changes to make this category consistent with Category 14.
Category 19 Permit application: possess or supply an unregistered product for export	<ul style="list-style-type: none"> paragraph 2.3.2: change title and text paragraph 2.4: change title minor text edits.
Category 20 Permit application: new permit where a previous assessment remains valid	<ul style="list-style-type: none"> minor text edits.
Category 21 Permit application: minor use	<ul style="list-style-type: none"> minor text edits.
Category 22 Permit application: emergency use	<ul style="list-style-type: none"> paragraph 2.2: expansion of text to provide more information minor text edits.
Category 23 Permit application: research use	<ul style="list-style-type: none"> minor text edits.
Category 24 Registration of a product, not covered by any other Category	<ul style="list-style-type: none"> paragraph 2.3: revised label requirements edit paragraph 2.5 to explain that a data list and Module 12 are now required for applications involving chemistry assessment only edit Example 1 to show that Module 12 (data protection) applies.
Category 25 Pre-approval assessment Trial protocol Application requiring technical assessment and not covered by any other Category	<ul style="list-style-type: none"> no changes.
Definition of terms used in this manual	<ul style="list-style-type: none"> LOQ: correct an error in the definition.
Acronyms used in this manual	<ul style="list-style-type: none"> DEH updated to reflect Departmental name change.

MORAG DOCUMENT	REVISIONS
Volume 3	
Module levels for modular categories	<ul style="list-style-type: none"> • edits to be consistent with revisions to Part 2.
Part 1 Application overview	<ul style="list-style-type: none"> • change to presentation and minor text edits.
Part 2 Chemistry and manufacture	<ul style="list-style-type: none"> • complete revision of all text.
Part 3 Toxicology	<ul style="list-style-type: none"> • provided references to OECD guidelines for dermal absorption studies • edit ARfD information to say that an ARfD is not always necessary.
Part 4 Metabolism and kinetics	<ul style="list-style-type: none"> • no changes.
Part 5A Residues	<ul style="list-style-type: none"> • no changes.
Part 5B Overseas trade aspects of residues in food commodities	<ul style="list-style-type: none"> • extensive revision of all text.
Part 6 Occupational health and safety	<ul style="list-style-type: none"> • minor text edits.
Part 7 Environment	<ul style="list-style-type: none"> • no changes.
Part 8 Efficacy and safety	<ul style="list-style-type: none"> • no changes.
Part 9 Other trade aspects	<ul style="list-style-type: none"> • no changes.
Part 10 Special data	<ul style="list-style-type: none"> • no changes.

MORAG DOCUMENT	REVISIONS
Volume 5	
Ag Labelling Code	<ul style="list-style-type: none">• moved carfentrazone-ethyl from Group F to Group G• minor text edits.
Label approval process	<ul style="list-style-type: none">• minor text edits.

APPLICATION FORMS

APPLICATION FORM	REVISIONS
<p>Application form home page on MORAG website</p>	<ul style="list-style-type: none"> complete redesign
<p>Category 1 or 2 New product with new active constituent</p>	<p>re-name so that the form is relevant only to agricultural products</p>
<p>Category 2 New product with new active constituent</p>	<ul style="list-style-type: none"> new form specifically for veterinary applications. Changes from previous Category 1 or 2 application form as follows: amend text of 'purpose of application and description of use' and correct error in weblink remove consent to use email for technical reports to be consistent with Commonwealth Government policies not to use email for commercially-confidential material add a declaration that the data list is accurate change section 5 (protected data) to include label version number change title of section 7 to be consistent with data protection guidelines; edit incorrect link to webpage edit section 11 to distinguish between new active constituents and existing active constituents and to include the data normally requested in the 'approval of a new active constituent' form change section 14 to require e-labels remove separate application form for approval of an active constituent
<p>Category 2 or 10 Veterinary immunobiologicals</p>	<ul style="list-style-type: none"> amend text of 'purpose of application and description of use' and correct error in weblink remove consent to use email for technical reports to be consistent with Commonwealth Government policies not to use email for commercially-confidential material add a declaration that the data list is accurate change section 5 (protected data) to include label version number change title of section 7 to be consistent with data protection guidelines; edit incorrect link to webpage edit section 11 to include the data normally requested in the 'approval of a new active constituent' form change section 14 to require e-labels remove separate application form for approval of an immunobiological active constituent

APPLICATION FORMS

APPLICATION FORM	REVISIONS
Category 3-7 or 10 Registration of a new product	<ul style="list-style-type: none"> • amend text of ‘purpose of application and description of use’ and correct error in weblink • remove consent to use email for technical reports to be consistent with Commonwealth Government policies not to use email for commercially-confidential material • amend text of ‘purpose of application and description of use’ and correct error in weblink • add a declaration that the data list is accurate • change section 4 (protected data) to include label version number • change title of section 7 to be consistent with data protection guidelines; edit incorrect link to webpage • change section 14 to require e-labels
Category 8 Repack	<ul style="list-style-type: none"> • change section 5 to require e-labels
Category 9 Listed registration	<ul style="list-style-type: none"> • form not available
Category 12 Change product details or copy reference product uses	<ul style="list-style-type: none"> • change section 4 (protected data) to include label version number • change section 11 to require e-labels
Category 12 or 13 Label change only	<ul style="list-style-type: none"> • additional cell to indicate the new product name, if the applicant proposes to change the product name • change section 5 to require e-labels
Category 11 or 14 Variation	<ul style="list-style-type: none"> • additional cell to indicate the new product name, if the applicant proposes to change the product name • correct error in weblink of ‘purpose of application and description of use’ • remove consent to use email for technical reports to be consistent with Commonwealth Government policies not to use email for commercially-confidential material • add a declaration that the data list is accurate • change section 5 (protected data) to include label version number • change title of section 7 to be consistent with data protection • change section 14 to require e-labels
Category 19 Export permit	<ul style="list-style-type: none"> • no changes.
Category 20 Permit where a previous assessment remains valid	<ul style="list-style-type: none"> • change title to make the purpose of the application more clear.
Category 21 Minor use permit	<ul style="list-style-type: none"> • complete revision

APPLICATION FORMS

APPLICATION FORM	REVISIONS
Category 22 Emergency use permit	<ul style="list-style-type: none"> complete revision
Category 23 Research permit	<ul style="list-style-type: none"> remove consent to use email for technical reports to be consistent with Commonwealth Government policies not to use email for commercially-confidential material
Category 23 Batch supply or label oversticker permit	<ul style="list-style-type: none"> no changes.
Category 24 Registration not under any other Category	<ul style="list-style-type: none"> amend text of 'purpose of application and description of use' and correct error in weblink add a declaration that the data list is accurate change section 5 (protected data) to include label version number change title of section 7 to be consistent with data protection
Category 25 Trial protocol assessment registration not under any other category	<ul style="list-style-type: none"> remove consent to use email for technical reports to be consistent with Commonwealth Government policies not to use email for commercially-confidential material
Category 25 Variation not in any other Category	<ul style="list-style-type: none"> additional cell to indicate the new product name, if the applicant proposes to change the product name correct error in weblink of 'purpose of application and description of use' remove consent to use email for technical reports to be consistent with Commonwealth Government policies not to use email for commercially-confidential material change section 4 (protected data) to include label version number change title of section 7 to be consistent with data protection change section 14 to require e-labels
Category 25 Other technical assessment	<ul style="list-style-type: none"> remove consent to use email for technical reports to be consistent with Commonwealth Government policies not to use email for commercially-confidential material