

CHANGES TO AG MORAG DOCUMENTS IN EDITION 4.1

| MORAG DOCUMENT | REVISIONS |
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| 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"> paragraph 2.3: revised label requirements 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: revised label requirements paragraph 2.6: edit re provision of data lists for chemistry data paragraph 3.1: remove reference to veterinary applications 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"> paragraph 2.3: revised label requirements minor text edits. |
| Category 4 Registration of a new product with an approved active constituent, for use on a major food crop | <ul style="list-style-type: none"> paragraph 2.2: remove reference to requirement for a new modular application including screening, if new data are required paragraph 2.3: revised label requirements minor text changes. |

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| <p>Category 5 Registration of a product which is similar to a registered product: chemistry and efficacy assessment required</p> | <ul style="list-style-type: none"> • paragraph 1.1: edit to clarify the definition of ‘similar’ with respect to active constituents • 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. |
| <p>Category 6</p> | <ul style="list-style-type: none"> • paragraph 1.1: edit to clarify the definition of ‘similar’ with respect to active constituents • 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. |
| <p>Category 7</p> | <ul style="list-style-type: none"> • paragraph 1.1: edit to clarify the definition of ‘similar’ with respect to active constituents • 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. |
| <p>Category 8 Repack of a registered product</p> | <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. • 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 • paragraph 2.8 correction to wording • minor text edits. |
| <p>Category 9 Listed registration</p> | <ul style="list-style-type: none"> • removed the requirement to provide a draft label in paragraph 2.2 • minor text edits. |
| <p>Category 10 Registration of a new product: modular assessment</p> | <ul style="list-style-type: none"> • paragraph 2.3: revised label requirements • edit old paragraph 2.6 re provision of data lists for chemistry data • add 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. |
| <p>Category 11 Not relevant to veterinary applications</p> | <ul style="list-style-type: none"> • paragraph 2.3: revised label requirements • minor text edits. |

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| <p>Category 12 Minor variation where no technical data are required</p> | <ul style="list-style-type: none"> • paragraph 2.2: change to label requirements re e-labels • 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 • 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 • paragraph 4.5.2: edit to refer to Category 12 for certain variations to non-active constituents • minor text edits. |
| <p>Category 15 Approval of a new active constituent</p> | <ul style="list-style-type: none"> • minor text edits. |
| <p>Category 16 Approval of a new active constituent: limited toxicology assessment</p> | <ul style="list-style-type: none"> • paragraph 2.3: correct error in fee • minor text edits. |
| <p>Category 17 Approval of a new active constituent: toxicology assessment not required</p> | <ul style="list-style-type: none"> • paragraph 2.4: edit to now require a chemistry data list • minor text edits. |
| <p>Category 18 Variation to an active constituent</p> | <ul style="list-style-type: none"> • paragraph 1.1: change title • minor text edits. |
| <p>Category 19 Permit application: possess or supply an unregistered product for export</p> | <ul style="list-style-type: none"> • paragraph 2.3.2: change title and text • paragraph 2.4: change title • minor text edits. |
| <p>Category 20 Permit application: new permit where a previous assessment remains valid</p> | <ul style="list-style-type: none"> • minor text edits. |
| <p>Category 21 Permit application: minor use</p> | <ul style="list-style-type: none"> • minor text edits. |

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| 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 • paragraph 2.5: edit to explain that a data list and Module 12 are now required for applications involving chemistry assessment only • Example 1: edit 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"> • complete revision of all text. |
| 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 to DEW. |

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| 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"> • no changes. |
| 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"> • entry to say that this data Part is rarely relevant to agricultural applications. |
| Part 10 Special data | <ul style="list-style-type: none"> • entry to say that this data Part is rarely relevant to agricultural applications. |
| 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 |
|---|--|
| Application form home page on MORAG website | <ul style="list-style-type: none"> • complete redesign. |
| Category 1 or 2 New product with new active constituent | <ul style="list-style-type: none"> • re-name so that the form is relevant only to agricultural products • 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 • remove reference to veterinary products in section 9 • delete section 10 re Good Manufacturing Practice because it is relevant to veterinary applications only • change section 14 to require e-labels. |
| 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"> • change section 5 to require e-labels. |
| Category 11 or 14 Variation | <ul style="list-style-type: none"> • 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. |

APPLICATION FORMS

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| 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. |
| 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. |
| Batch supply or label over sticker permit | 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 | <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 complete revision of all text. |
| Category 25 Variation not in any other Category | <ul style="list-style-type: none"> 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. |