

## CHANGES TO VET MORAG DOCUMENTS IN EDITION 4.1

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

MORAG DOCUMENT	REVISIONS
<b>Category 4</b> Not relevant to veterinary applications	<ul style="list-style-type: none"> <li>no changes.</li> </ul>
<b>Category 5</b> Registration of a product which is similar to a registered product: chemistry and efficacy assessment required	<ul style="list-style-type: none"> <li>paragraph 2.3: revised label requirements</li> <li>paragraph 2.5: removed inaccurate reference to Module 12. Edited to state that applicants must provide a Data List for chemistry and manufacture data</li> <li>minor text edits.</li> </ul>
<b>Category 6</b>	<ul style="list-style-type: none"> <li>paragraph 2.3: revised label requirements</li> <li>paragraph 2.5: edited to state that applicants must provide a Data List for chemistry and manufacture data</li> <li>minor text edits.</li> </ul>
<b>Category 7</b>	<ul style="list-style-type: none"> <li>paragraph 1.2: refer to pioneer reference product</li> <li>paragraph 2.2: new paragraph added to state that data are not required</li> <li>paragraph 2.3: revised label requirements</li> <li>minor text edits.</li> </ul>
<b>Category 8</b> Repack of a registered product	<ul style="list-style-type: none"> <li>add new paragraph 2.2.1 re EARS</li> <li>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.</li> <li>paragraph 2.5: revised label requirements</li> <li>paragraph 2.8: correction to wording</li> <li>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</li> <li>minor text edits.</li> </ul>
<b>Category 9</b> Listed registration	<ul style="list-style-type: none"> <li>removed the requirement to provide a draft label in paragraph 2.2</li> <li>minor text edits.</li> </ul>
<b>Category 10</b> Registration of a new product: modular assessment	<ul style="list-style-type: none"> <li>paragraph 2.3: revised label requirements</li> <li>insert new paragraph 2.6 re public consultation</li> <li>edit paragraph 2.7 (previously paragraph 2.6) re provision of data lists for chemistry data</li> <li>minor text edits.</li> </ul>
<b>Category 11</b> Not relevant to veterinary applications	<ul style="list-style-type: none"> <li>no changes.</li> </ul>

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

MORAG DOCUMENT	REVISIONS
<b>Category 18</b> Variation to an active constituent	<ul style="list-style-type: none"> <li>changes to make this category consistent with Category 14.</li> </ul>
<b>Category 19</b> Permit application: possess or supply an unregistered product for export	<ul style="list-style-type: none"> <li>paragraph 2.3.2: change title and text</li> <li>paragraph 2.4: change title</li> <li>minor text edits.</li> </ul>
<b>Category 20</b> Permit application: new permit where a previous assessment remains valid	<ul style="list-style-type: none"> <li>minor text edits.</li> </ul>
<b>Category 21</b> Permit application: minor use	<ul style="list-style-type: none"> <li>minor text edits.</li> </ul>
<b>Category 22</b> Permit application: emergency use	<ul style="list-style-type: none"> <li>paragraph 2.2: expansion of text to provide more information</li> <li>minor text edits.</li> </ul>
<b>Category 23</b> Permit application: research use	<ul style="list-style-type: none"> <li>minor text edits.</li> </ul>
<b>Category 24</b> Registration of a product, not covered by any other Category	<ul style="list-style-type: none"> <li>paragraph 2.3: revised label requirements</li> <li>edit paragraph 2.5 to explain that a data list and Module 12 are now required for applications involving chemistry assessment only</li> <li>edit Example 1 to show that Module 12 (data protection) applies.</li> </ul>
<b>Category 25</b> Pre-approval assessment Trial protocol Application requiring technical assessment and not covered by any other Category	<ul style="list-style-type: none"> <li>complete revision of all text.</li> </ul>
<b>Definition of terms used in this manual</b>	<ul style="list-style-type: none"> <li>LOQ: correct an error in the definition.</li> </ul>
<b>Acronyms used in this manual</b>	<ul style="list-style-type: none"> <li>DEH updated to reflect departmental name change to DEW.</li> </ul>

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

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MORAG DOCUMENT	REVISIONS
<b>Volume 5</b>	
Vet Labelling Code	<ul style="list-style-type: none"><li>• no changes.</li></ul>
Label approval process	<ul style="list-style-type: none"><li>• minor text edits.</li></ul>

## APPLICATION FORMS

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

## APPLICATION FORMS

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

## APPLICATION FORMS

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