

## Revisions to Ag MORAG documents for edition 3

MORAG document	Revisions
Most documents in Volumes 1, 2, 3 and 5	<ul style="list-style-type: none"> <li>format changed to .html</li> </ul>
<b>Volume 1</b>	
Introduction to MORAG	<ul style="list-style-type: none"> <li>no changes.</li> </ul>
Legal background to the National Registration Scheme	<ul style="list-style-type: none"> <li>updated link to Agvet Code Regulations.</li> </ul>
Procedures for making an application	<ul style="list-style-type: none"> <li>paragraph 4.1 (data) and 4.5 (binding): added statement that different data parts must be submitted as separate bound volumes</li> <li>paragraph 4.2: changed addressee for submitting applications</li> <li>paragraph 5.3: edited to clarify the treatment of applications that do not pass screening</li> <li>added new paragraphs 5.3.2 and 5.3.3 on treating applications as having been withdrawn, and rejecting applications</li> <li>added new paragraph 5.4.4 to explain the difference between clock time and elapsed time.</li> </ul>
Legislative Instruments	<ul style="list-style-type: none"> <li>no changes.</li> </ul>
<b>Volume 2</b>	
How to use Volume 2	<ul style="list-style-type: none"> <li>old and new category comparison table (Annexe A): old category 44 corrected to correspond to new Category 21 (modular).</li> </ul>
Category 1	<ul style="list-style-type: none"> <li>paragraph 2: added reference to data list.</li> </ul>
Category 2	<ul style="list-style-type: none"> <li>paragraph 2: added reference to data list</li> <li>paragraph 2.6: clarified data protection for secondary applications.</li> </ul>
Category 3	<ul style="list-style-type: none"> <li>paragraph 2: added reference to data list.</li> </ul>
Category 4	<ul style="list-style-type: none"> <li>paragraph 2: added reference to data list.</li> </ul>
Category 5	<ul style="list-style-type: none"> <li>paragraph 1.1: moved paragraph from 1.2 on products not similar</li> <li>paragraph 1.2: added statement that a product which is the subject of an application for registration cannot be a reference product</li> <li>paragraph 2: added reference to data list.</li> </ul>
Category 6	<ul style="list-style-type: none"> <li>paragraph 1.1: moved paragraph from 1.2 on products not closely similar</li> <li>paragraph 1.2: added statement that a product which is the subject of an application for registration cannot be a reference product</li> <li>paragraph 2.5: changed reference to data list.</li> </ul>
Category 7	<ul style="list-style-type: none"> <li>paragraph 1.2: added statement that a product which is the subject of an application for registration cannot be a reference product.</li> </ul>

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Category 8	<ul style="list-style-type: none"> <li>• paragraph 1.2: added statement that a product which is the subject of an application for registration cannot be a reference product</li> <li>• added paragraph 1.3 – referring to confidential commercial information</li> <li>• paragraph 2.2: sentence added about formulator’s declaration where the applicant and formulator are part of the same company structure</li> <li>• added paragraph heading 2.3 for Applicant’s declaration.</li> </ul>
Category 9	<ul style="list-style-type: none"> <li>• inserted notice that this category is currently unavailable.</li> </ul>
Category 10	<ul style="list-style-type: none"> <li>• paragraph 2: added reference to data list</li> <li>• added paragraph 2.5 – use of reference products</li> <li>• paragraph 2.6: clarified data protection for secondary applications.</li> </ul>
Category 11	<ul style="list-style-type: none"> <li>• paragraph 2: added reference to data list.</li> </ul>
Category 12	<ul style="list-style-type: none"> <li>• amended title of paragraph 3.1.1.</li> </ul>
Category 13	<ul style="list-style-type: none"> <li>• no changes.</li> </ul>
Category 14	<ul style="list-style-type: none"> <li>• paragraph 2: added reference to data list</li> <li>• added paragraph 2.5 – use of reference products</li> <li>• paragraph 2.7: clarified data protection for secondary applications</li> <li>• changed heading name of paragraph 4.</li> </ul>
Category 15	<ul style="list-style-type: none"> <li>• paragraph 2: added reference to data list.</li> </ul>
Category 16	<ul style="list-style-type: none"> <li>• paragraph 2: added reference to data list.</li> </ul>
Category 17	<ul style="list-style-type: none"> <li>• paragraph 2.4: changed reference to data list.</li> </ul>
Category 18	<ul style="list-style-type: none"> <li>• no changes.</li> </ul>
Category 19	<ul style="list-style-type: none"> <li>• paragraph 1: minor typographical error corrected.</li> </ul>
Category 20	<ul style="list-style-type: none"> <li>• paragraph 1 and 1.1: emergency use permits cannot be extended</li> <li>• added paragraph 2.1.1: description of Australian, State or Territory government business that qualifies for fee exemption.</li> </ul>
Category 21	<ul style="list-style-type: none"> <li>• added paragraph 2.4.1: description of Australian, State or Territory government business that qualifies for fee exemption.</li> </ul>
Category 22	<ul style="list-style-type: none"> <li>• added paragraphs 3.2 and 3.3 relating to permit duration and extension.</li> </ul>
Category 23	<ul style="list-style-type: none"> <li>• added paragraph 2.4.1: description of Australian, State or Territory government business that qualifies for fee exemption.</li> </ul>
Category 24	<ul style="list-style-type: none"> <li>• paragraph 2: added reference to data list.</li> </ul>

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Category 25	<ul style="list-style-type: none"> <li>paragraph 3: added caveat regarding results obtained from trials.</li> </ul>
Definition of terms used in this manual	<ul style="list-style-type: none"> <li>additional definitions of major and minor food-producing animals</li> <li>minor change to definition of closely similar veterinary products.</li> </ul>
Acronyms used in this manual	<ul style="list-style-type: none"> <li>added FDA.</li> </ul>
<b>Volume 3</b>	
Module levels for modular categories	<ul style="list-style-type: none"> <li>reference to 'pharmaceutical dosage form' deleted from Chemistry Module 2 tables</li> <li>Module tables: added reference to Data Parts for detailed requirements</li> <li>Module 2.4: changed wording of application type involving only stability <math>\pm</math> product specifications</li> <li>Module 3 Toxicology tables: data elements modified to reflect revised Part 3</li> <li>Module 6 OH&amp;S tables: data elements modified to reflect revised Part 6.</li> </ul>
Part 1 Application Overview	<ul style="list-style-type: none"> <li>paragraph 2.3 [1.5]: changed instruction to include summary section of Part 5A and Part 5B under subpart 1.5</li> <li>paragraph 2.3 [1.8]: changed instruction to include summary section of Part 8 under subpart 1.8</li> <li>paragraph 3 [1.1e]: clarified text concerning overseas applications.</li> </ul>
Part 2 Chemistry and Manufacture	<ul style="list-style-type: none"> <li>no changes.</li> </ul>
Part 3 Toxicology	<ul style="list-style-type: none"> <li>complete revision of the content.</li> </ul>
Part 4 Metabolism and Kinetics	<ul style="list-style-type: none"> <li>no changes.</li> </ul>
Part 5A Residues	<ul style="list-style-type: none"> <li>no changes.</li> </ul>
Part 5B Overseas Trade Aspects of Residues in Food Commodities	<ul style="list-style-type: none"> <li>updated hyperlink to Japanese agricultural chemical MRLs.</li> </ul>
Part 6 Occupational Health and Safety	<ul style="list-style-type: none"> <li>complete revision of the content.</li> </ul>
Part 7 Environment	<ul style="list-style-type: none"> <li>no changes.</li> </ul>
Part 8 Efficacy and Safety	<ul style="list-style-type: none"> <li>no changes.</li> </ul>

MORAG document	Revisions
<b>Volume 5</b>	
Ag Labelling Code	<ul style="list-style-type: none"> <li>corrected references to 'NRA'</li> <li>chapter 3: subheadings renumbered.</li> </ul>
Label approval process	<ul style="list-style-type: none"> <li>no changes.</li> </ul>

Application form	Revisions
Application form home page	<ul style="list-style-type: none"> <li>added link to notes/tips on use of application forms.</li> </ul>
All forms except for Categories 12 or 13 (label change only), 19, 20-23 and 25 (trial protocol / pre-registration/approval assessment)	<ul style="list-style-type: none"> <li>updated links to data protection pages on website.</li> </ul>
All forms except for Categories 12, 13, 15-23, 25 (trial protocol / pre-registration/approval assessment)	<ul style="list-style-type: none"> <li>page 1 'Purpose of application and description of use': added link to website guideline, and added fields for standard statements where relevant.</li> </ul>
Forms for Categories 1-7, 10, 11, 14 and 22-25	<ul style="list-style-type: none"> <li>page 1: added consent field for electronic transmission of technical reports</li> <li>overview template section: changed instruction to include summary sections of Part 5A and Part 5B under subpart 1.5, and of Part 8 under subpart 1.8.</li> </ul>
Category 3-7 or 10 form	<ul style="list-style-type: none"> <li>section 13: added note that stability data are not required for Category 7 applications.</li> </ul>
Category 12 (change product details form)	<ul style="list-style-type: none"> <li>page 1: added purpose of application</li> <li>page 2: deleted 'distinct use' section.</li> </ul>
Category 22 (emergency use permit form)	<ul style="list-style-type: none"> <li>page 1: replace fee field with 'Nil'</li> <li>section 4: added active constituent name and concentration fields</li> </ul>
	5 June 2006 (version 3.1)
	<ul style="list-style-type: none"> <li>section 8: 'trial use' corrected to 'emergency use'.</li> </ul>

Module calculator	Revisions
Calculator	<ul style="list-style-type: none"> <li>'Module help' button: target links changed to relevant sections of 'Module levels for modular categories'.</li> </ul>