

Revisions to Vet MORAG documents for edition 3

MORAG document	Revisions
Most documents in Volumes 1, 2, 3 and 5	<ul style="list-style-type: none"> format changed to .html
Volume 1	
Introduction to MORAG	<ul style="list-style-type: none"> no changes.
Legal background to the National Registration Scheme	<ul style="list-style-type: none"> updated link to Agvet Code Regulations.
Procedures for making an application	<ul style="list-style-type: none"> paragraph 4.1 (data) and 4.5 (binding): added statement that different data parts must be submitted as separate bound volumes paragraph 4.2: changed addressee for submitting applications paragraph 5.3: edited to clarify the treatment of applications that do not pass screening added new paragraphs 5.3.2 and 5.3.3 on treating applications as having been withdrawn, and rejecting applications added new paragraph 5.4.4 to explain the difference between clock time and elapsed time.
Legislative Instruments	<ul style="list-style-type: none"> no changes.
Volume 2	
How to use Volume 2	<ul style="list-style-type: none"> old and new category comparison table (Annexe A): old category 44 corrected to correspond to new Category 21 (modular).
Category 1	<ul style="list-style-type: none"> no changes.
Category 2	<ul style="list-style-type: none"> paragraph 2: added reference to data list paragraph 2.6 and examples: clarified data protection for secondary applications changed heading name of paragraph 4 paragraph 4.1: added example of primary and secondary applications involving several products with different dosage forms.
Category 3	<ul style="list-style-type: none"> no changes.
Category 4	<ul style="list-style-type: none"> no changes.
Category 5	<ul style="list-style-type: none"> paragraph 1.1: moved paragraph from 1.2 on products not similar paragraph 1.2: added statement that a product which is the subject of an application for registration cannot be a reference product paragraph 1.3: added exclusions for DNA constructs and biological delivery systems paragraph 2: added reference to data list.

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Category 6	<ul style="list-style-type: none"> • paragraph 1.1: definition revised to clarify pharmaceutical equivalence and moved paragraph from 1.2 on products not closely similar • paragraph 1.2: added statement that a product which is the subject of an application for registration cannot be a reference product • paragraph 1.3: added exclusions for DNA constructs, biological delivery systems and solid transdermal dosage forms • paragraph 2.5: changed reference to data list.
Category 7	<ul style="list-style-type: none"> • paragraph 1.1: deletion of reference to pharmaceutical equivalence • paragraph 1.2: added statement that a product which is the subject of an application for registration cannot be a reference product • paragraph 1.3 (ineligible product types) deleted.
Category 8	<ul style="list-style-type: none"> • paragraph 1.2: added statement that a product which is the subject of an application for registration cannot be a reference product • added paragraph 1.3 – referring to confidential commercial information • paragraph 2.2: sentence added about formulator’s declaration where the applicant and formulator are part of the same company structure • added paragraph heading 2.3 for Applicant’s declaration.
Category 9	<ul style="list-style-type: none"> • inserted notice that this category is currently unavailable.
Category 10	<ul style="list-style-type: none"> • paragraph 2: added reference to data list • added paragraph 2.5 – use of reference products • paragraph 2.6: clarified data protection for secondary applications • changed heading name of paragraph 4.
Category 11	<ul style="list-style-type: none"> • no changes.
Category 12	<ul style="list-style-type: none"> • amended title of paragraph 3.1.1 • paragraph 3.2.2: added clarification that changes involving overseas formulators require application under Category 14 • amended the title and introductory text of Appendix A and re-numbered it as section 4.
Category 13	<ul style="list-style-type: none"> • no changes.
Category 14	<ul style="list-style-type: none"> • paragraph 2: added reference to data list • added paragraph 2.5 – use of reference products • paragraph 2.7: clarified data protection for secondary applications • changed heading name of paragraph 4.
Category 15	<ul style="list-style-type: none"> • paragraph 2: added reference to data list.
Category 16	<ul style="list-style-type: none"> • paragraph 2: added reference to data list.
Category 17	<ul style="list-style-type: none"> • paragraph 1.2 added relating to ectoparasiticide active constituents • paragraph 2.4: changed reference to data list.

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Category 18	<ul style="list-style-type: none"> no changes.
Category 19	<ul style="list-style-type: none"> paragraph 1: minor typographical error corrected.
Category 20	<ul style="list-style-type: none"> paragraph 1: added clarification regarding emergency use permits added paragraph 2.1.1: description of Australian, State or Territory government business that qualifies for fee exemption.
Category 21	<ul style="list-style-type: none"> added paragraph 2.4.1: description of Australian, State or Territory government business that qualifies for fee exemption.
Category 22	<ul style="list-style-type: none"> added paragraphs 3.2 and 3.3 relating to permit duration and extension.
Category 23	<ul style="list-style-type: none"> paragraph 2.2.1: added statement that animal experimenters must be registered/licensed added paragraph 2.5.1: description of Australian, State or Territory government business that qualifies for fee exemption paragraph 4.1.1: added hyperlink to guideline for extension of shelf life of a particular batch of product.
Category 24	<ul style="list-style-type: none"> paragraph 2: added reference to data list.
Category 25	<ul style="list-style-type: none"> paragraph 3: added caveat regarding results obtained from trials paragraph 3.2.1: added note that animal experimenters must be registered/licensed.
Definition of terms used in this manual	<ul style="list-style-type: none"> additional definitions of major and minor food-producing animals minor change to definition of closely similar veterinary products.
Acronyms used in this manual	<ul style="list-style-type: none"> added FDA.
Volume 3	
Module levels for modular categories	<ul style="list-style-type: none"> minor typographical errors corrected in paragraphs 1.1, 1.5.1 and 1.5.9 Module tables: added reference to Data Parts for detailed requirements Module 2.4: changed wording of application type involving only stability \pm product specifications Module 3 Toxicology tables: data elements modified to reflect revised Part 3 Module 6 OH&S tables: data elements modified to reflect revised Part 6. Module 8 Efficacy & host animal safety tables: data elements modified to reflect revised Part 8 Module 8.3: changed wording of in vitro dissolution application type Modules 10.1 and 10.2: Antibiotic resistance tables: data elements modified to reflect revised Part 10.

MORAG document	Revisions
Part 1 Application Overview	<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.
Part 2 Chemistry and Manufacture	<ul style="list-style-type: none"> no changes.
Part 3 Toxicology	<ul style="list-style-type: none"> complete revision of the content.
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"> updated hyperlink to Japanese agricultural chemical MRLs.
Part 6 Occupational Health and Safety	<ul style="list-style-type: none"> complete revision of the content.
Part 7 Environment	<ul style="list-style-type: none"> no changes.
Part 8 Efficacy and Safety	<ul style="list-style-type: none"> complete revision of content.
Part 9 Other Trade Aspects	<ul style="list-style-type: none"> no changes.
Part 10 Special Data	<ul style="list-style-type: none"> correlation of data requirements with EMEA VICH guideline #27 revised introduction, objectives and scope added references to FDA and EMEA guidelines more detail provided for risk assessments in non-food-producing animals.
Volume 5	
Vet Labelling Code	<ul style="list-style-type: none"> corrected references to 'NRA' and minor typographical errors paragraph 1.5: added reference to Label Approval Process paragraph 2.24: added pack size identifier to APVMA approval number.
Label approval process	<ul style="list-style-type: none"> no changes.

Application form	Revisions
Application form home page	<ul style="list-style-type: none"> added link to notes/tips on use of application forms.
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"> updated links to data protection pages on website.
All forms except for Categories 12, 13, 15-23, 25 (trial protocol / pre-registration/approval assessment)	<ul style="list-style-type: none"> page 1 'Purpose of application and description of use': added link to website guideline, and added fields for standard statements where relevant.
Forms for Categories 1-7, 10, 11, 14, 21-25 and immunobiologicals	<ul style="list-style-type: none"> page 1: added consent field for electronic transmission of technical reports 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.
Category 3-7 or 10 form	<ul style="list-style-type: none"> section 13: added note that stability data are not required for Category 7 applications.
Category 12 (change product details form)	<ul style="list-style-type: none"> page 1: added purpose of application page 2: deleted 'distinct use' section.
Category 22 (emergency use permit form)	<ul style="list-style-type: none"> page 1: replace fee field with 'Nil' section 4: added active constituent name and concentration fields
	5 June 2006 (version 3.1) <ul style="list-style-type: none"> section 8: 'trial use' corrected to 'emergency use'.

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