This is a list of guidelines for the safety of veterinary medicines as issued by the European Medicines Agency (EMA) and the International Veterinary Conference on Harmonization (VICH).

The page is structured and contains instructions from the field of toxicology, user safety, environmental safety, and guidance on residue safety assessment (lead times, MRLs). Please click here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000384.jsp&mid=WC0b01ac058002dd37

In addition to the guidelines mentioned below, the EMA also publishes and updates a list of frequently asked questions and answers concerning MRL determination, please click here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000039.jsp&mid=WC0b01ac058002d89b

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List of scientific guidelines on the safety - part III.A :

TOXICOLOGY

Name	Number	Effective from	Note
VICH GL22 Safety studies for veterinary drug residues in human food: reproduction studies	CVMP/VICH/502/2000	01/07/2002	Final
VICH GL23 Studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicit	CVMP/VICH/526/2000	01/10/2015	Rev 1
VICH GL28 Studies to evaluate the safety of residues of veterinary drugs in human: carcinogenicity testing	CVMP/VICH/645/2001	01/03/2006	Rev 1
VICH GL31 Safety studies for veterinary drug residues in human food: repeat-dose (90) toxicity testin	CVMP/VICH/484/2002	01/06/2004	Final
VICH GL32 Studies to evaluate the safety of residues of veterinary drugs in human food: developme	CVMP/VICH/485/2002	Final Adopted by CV	
VICH GL33 Safety studies for veterinary drug residues in human food: general approach to testing	EMEA/CVMP/VICH/436/2003	01/02/2011	Rev 2
VICH GL37 Safety of veterinary drugs in human food: repeat dose (chronic) toxicity testing	CVMP/VICH/468/2003	30/05/2005	Final
VICH GL54 Studies to evaluate the safety of residues of veterinary drugs in human food: general ap	EMA/CVMP/VICH/599251/2011	01/01/2017	-
Assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products	EMA/CHMP/CVMP/SWP/378415/2016	Draft guideline	
Regulatory acceptance of 3R (Replacement, Reduction, Refinement) testing approaches	EMA/CHMP/CVMP/JEG-3Rs/450688/2012	-	

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USER SAFETY

Name	Number	Effective from	Note
User safety for pharmaceutical veterinary medicinal products	EMEA/CVMP/543/2003-Rev1	01/10/2010	Rev. 1
User safety of topically administered products	EMA/CVMP/SWP/721059/2014		Draft guideline

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ENVIRONMENTAL RISK ASSESSMENT

Name	Number	Effective from	Note
VICH GL6 Environmental impact assessment (EIAS) for veterinary medicinal products - Phase I	CVMP/VICH/592/1998	20/07/2000	Guideline
VICH GL38 Environmental impact assessment for veterinary medicinal products - Phase II	CVMP/VICH/790/2003	01/10/2005	Guideline
Environmental impact assessment for veterinary medicinal products in support of the VICH Guideline	EMEA/CVMP/ERA/418282/2005-Rev.1	20/09/2018	Rev. 1
Assessment of persistent, bioaccumulative and toxic (PBT) / very persistent and very bioaccumulati	EMA/CVMP/ERA/52740/2007-Rev.2	04/02/2016	Guideline
Authorisation of veterinary medicinal products containing (potential) persistent, bioaccumulative and	EMA/CVMP/448211/2015		Reflection paper
Determining the fate of veterinary medicinal products in soil	EMA/CVMP/ERA/430327/2009	20/01/2011	Guideline
Higher-tier testing of veterinary medicinal products to dung fauna	EMA/CVMP/ERA/409350/2010		Draft guideline
Higher tier testing to investigate the effects of parasiticidal veterinary medicinal products on dung fau	EMA/CVMP/ERA/87473/2021		Reflection paper
Plant testing strategy for veterinary medicinal product			
EMA/CVMP/ERA/689041/2015	20/10/2017	Guideline	
Assessing the environmental and human health risks of veterinary medicinal products to groundwate	EMA/CVMP/ERA/103555/2018-Rev.1	21/11/2018	Guideline
Poorly extractable and/or non-extractable residues	EMA/CVMP/ERA/342254/2014		Reflection paper
Risk-mitigation measures related to the environmental risk assessment of veterinary medicinal produ	EMA/CVMP/ERA/409388/2016		Reflection paper
ERA - QaA document implementation of CVMP Guideline on environmental impact assessment for v	EMEA/CVMP/ERA/72074/2008-Rev.7		Q&A Rev. 7
Antimicrobial resistance in the environment			
EMEA/CVMP/ERA/632109/2014			
Reflection paper			
ERA-QaA document in support of the guideline on the assessment of persistent, bioaccumulative and to	EMA/593389/2019		Q&A
Interpretation of Article 18(7) of Regulation (EC) 726/2004	EMA/CVMP/ERA/622042/2006		Reflection paper
Interpretation of Article 7 of Regulation (EC) 726/2004	EMA/CVMP/ERA/145201/2021		Reflection paper
Criteria for determining that an active substance is essential when considered in the context of Article 37	EMA/CVMP/165132/2021		Draft Reflection paper

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List of scientific guidelines on the safety - part III.B :

RESIDUES/WITHDRAWAL PERIODS

Name	Number	Effective from	Note
Approach towards harmonisation of withdrawal periods	EMEA/CVMP/036/1995	01/01/1997	Under revision
Updated application software: withdrawal time calculation for tissues			web page EMA
Determination of withdrawal periods for milk	EMEA/CVMP/473/1998	08/09/2000	Under revision
Updated application software: withdrawal time calculation for milk			web page EMA
Injection-site residues	EMEA/CVMP/542/2003	13/04/2005	-
Setting health based exposure limits for use in risk assessment of residues in the manufacture of different medicina	EMA/CHMP/CVMP/SWP/169430/2012		Under revision
VICH GL46 studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producin	EMEA/CVMP/VICH/463678/2009		
VICH GL47 studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producin	EMEA/CVMP/VICH/463691/2009		
VICH GL48 studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producin	EMEA/CVMP/VICH/463698/2009		
VICH GL49 studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producin	EMEA/CVMP/VICH/463702/2009		
VICH GL56 studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producin	EMA/CVMP/VICH/376374/2009		Draft
VICH GL57 on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-produ	EMA/CVMP/VICH/517158/2011		Draft
Injection-site residues: considerations for risk assessment and residue surveillance	EMA/CVMP/520193/2008		Reflection papers
Introducing a review and update of existing guidelines on residues studies to bring these into line wit	EMA/CVMP/SWP/828285/2011		Concept paper

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MAXIMUM RESIDUE LIMITS (MRL´S)

Name	Number	Effective from	Note
Approach to establish a pharmacologically acceptable daily intake (ADI)	CVMP/SWP/055689/2006	01/06/2013	-
Data to be provided in support of a request to include a substance in the list of substances considered	EMEA/CVMP/518817/2009	01/03/2011	-
Risk-analysis approach for residues of VMPs in food of animal origin	EMEA/CVMP/187/00	10/04/2001	-
VICH GL36 Studies to evaluate the safety of residues of veterinary drugs in human food: General app	EMA/CVMP/VICH/463208/2008	01/05/2012	
Assessment of bioavailability of bound residues of animal origin in the context	EMEA/CVMP/SWP/569282/2007		Reflection papers
Consideration of adjuvants and preservatives under Council Regulation (EEC) No 2377/90	CVMP/339116/2007	17/12/2007	Reflection papers
New approach developed by the Joint Food and Agriculture Organization/World Health Organization	CVMP/138366/2006	28/09/2008	Reflection paper
Approaches on how to consider excipients in a Regulation 2377/90	EMEA/CVMP/223015/2005	01/12/2005	Concept paper
Definition of substances capable of pharmacological action in the context of Council Directive 2001/82	CVMP/032/1997-Rev1	30/04/2010	Position Paper
Establishment of maximum residue limits (MRLs) considering the daily intake by children	EMEA/CVMP/891/2002	01/11/2002	Position Paper

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AVAILABILITY (MINOR USES / MINOR SPECIES)

Name	Number	Effective from	Note
Guideline on safety and residue data requirements for pharmaceutical veterinary medicinal produc	EMA/CVMP/SWP/88781/2008-Rev2	08/12/2016	-
Note regarding CVMP guideline on data requirements for veterinary medicinal products intended f	EMEA/CVMP/133672/2005-Rev1	01/07/2006	-
Establishment of MRLs for Salmonidae other than fin fish	EMEA/CVMP/153U/97	01/01/1998	-
Position paper regarding availability of veterinary medicinal products - extrapolation of maximum res	EMEA/CVMP/457/03	10/12/2003	-

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MULTIDISCIPLINARY

Name	Number	Effective from	Note
Guideline on pharmaceutical fixed combination products	EMEA/CVMP/33804/05	18/12/2006	-
Investigation of chiral active substances	III/3501/91	01/10/1993	-

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