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/525/2000	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	01/12/2005	Final Adopted by CV
VICH GL33 Safety studies for veterinary drug residues in human food: general approach to testing	EMEA/CVMP/VICH/496/2003	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/377945/2016	01/01/2018	Draft guideline
Regulatory acceptance of 3R (Replacement, Reduction, Refinement) testing approaches	EMA/CHMP/CVMP/JEG-3Rs/450688/2012	01/01/2014	-

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USER SAFETY

Name	Number	Effective from	Note
User safety for pharmaceutical veterinary medicinal products	EMEA/CVMP/543/2003-Rev.1	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	20/09/2012	Rev. VICH guideline
Assessment of persistent, bioaccumulative and toxic (PBT) / very persistent and very bioaccumulati	EMA/CVMP/ERA/52740/2007-Rev.4	07/04/2016	Guideline
Authorisation of veterinary medicinal products containing (potential) persistent, bioaccumulative and	EMA/CVMP/448211/2015		Reflection paper
Determining the fate of veterinary medicinal products	EMA/CVMP/ERA/430327/2008	28/03/2011	Guideline
Higher tier testing to investigate effects of parasiticidal veterinary medicinal products on dung	EMA/CVMP/ERA/837473/2021		Reflection paper
Plant testing strategy for veterinary medicinal products	EMA/CVMP/ERA/689041/2015	20/10/2017	Guideline
Assessing the environmental and human health risks of veterinary medicinal products in groundwate	EMA/CVMP/ERA/110555/2014-Rev.1	20/09/2018	Guideline
Poorly extractable and/or non-recoverable residues	EMA/CVMP/ERA/349254/2014		Reflection paper
Risk-mitigation measures related to the environmental risk assessment of veterinary medicinal produ	EMA/CVMP/ERA/409328/2019		Reflection paper
ERA - QaA document implementation of CVMP Guideline on environmental impact assessment for v	EMEA/CVMP/ERA/172074/2008-Rev.7		Q&A Rev. 7
Antimicrobial resistance in the environment	EMEA/CVMP/ERA/632109/2014		Reflection paper
ERA-QaA document in support of guideline on the assessment of persistent, bioaccumulative and to	EMA/593389/2019		Q&A
Interpretation of Article 18(7) of Regulation (EU) 2019/6	EMA/CVMP/ERA/622045/2020		Reflection paper
Interpretation of Article 7 of Regulation (EU) 2019/6	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		Reflection paper
Environmental risk assessment of ectoparasiticidal veterinary medicinal products used in cats and dogs	EMA/CVMP/ERA/31905/2021	-	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 identification in the manufacture of different medicina	EMA/CHMP/CVMP/SWP/169430/2012	01/06/2015	Under revision
VICH GL46 studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producin	EMEA/CVMP/VICH/463072/2009	07/08/2012	
VICH GL47 studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producin	EMEA/CVMP/VICH/463104/2009	01/04/2012	
VICH GL48 studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producin	EMEA/CVMP/VICH/463199/2009	01/10/2016	
VICH GL49 studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producin	EMEA/CVMP/VICH/463202/2009	01/02/2016	
VICH GL56 studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producin	EMA/CVMP/VICH/176634/2014	24/03/2017	Draft
VICH GL57 on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-produ	EMA/CVMP/VICH/517152/2013	26/01/2018	Draft
Injection-site residues: considerations for risk assessment and residue surveillance	EMA/CVMP/520190/2007-Rev	30/09/2013	Reflection papers
Introducing a review and update of existing guidelines on residues studies to bring these into line wit	EMA/CVMP/SWP/882815/2012	25/01/2012	Concept papers

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MAXIMUM RESIDUE LIMITS (MRL´S)

Name	Number	Effective from	Note
Approach to establish a pharmacological acceptable daily intake (ADI)	CVMP/SWP/355689/2006	01/06/2013	-
Data to be provided in support of a request to include a substance in the list of substances considered	EMEA/CVMP/516817/2009	01/06/2011	-
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/467/2003	01/05/2012	
Assessment of bioavailability of bound residues in food commodities of animal origin in the context of	EMEA/CVMP/SWP/95682/2007	09/2008	Reflection papers
Consideration of adjuvants and preservatives under Council Regulation (EEC) No 2377/90 laying dow	CVMP/339116/2007	17/12/2007	Reflection papers
New approach developed by the Joint Food and Agriculture Organization/World Health Organization	CVMP/SWP/138366/2008	22/09/2008	Reflection papers
Approaches on how to consider excipients in the context of Regulation 2377/90	EMEA/CVMP/223005/2005	22/11/2005	Concept paper
Definition of substances capable of pharmacological action in the context of Council Directive 2001/82	CVMP/072/1997-Rev.1	30/04/2010	Position Paper
Establishment of maximum residue limits by considering the daily intake by children	EMEA/CVMP/391/2002	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/69781/2008-Rev.2	01/08/2016	-
Note regarding CVMP guidelines on data requirements for veterinary medicinal products intended f	EMEA/CVMP/123672/2005-Rev.2	01/07/2006	-
Establishment of MRLs for Salmonidae and other fin fish	EMEA/CVMP/153/97	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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