

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](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](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 drugs in food: reproduction	ICH/VICH/525/2000	07/2002	Final studies
VICH GL23 Studies to evaluate the safety of veterinary drugs in human food: genotoxicity	ICH/VICH/526/2000	01/10/2005	Revised
VICH GL28 Studies to evaluate the safety of veterinary drugs in human food: carcinogenicity testing	ICH/VICH/545/2001	01/10/2006	Genotoxicity testing
VICH GL31 Safety studies for veterinary drugs in food: repeat-dose (90) toxicity testing	ICH/VICH/484/2002	01/06/2004	Final
VICH GL32 Studies to evaluate the safety of veterinary drugs in human food: general approach to testing	ICH/VICH/485/2002	01/06/2004	Final Adopted by CVMP
VICH GL33 Safety studies for veterinary drugs in food: general approach to testing	ICH/VICH/486/2002	01/06/2004	Approach to testing
VICH GL37 Safety of veterinary drugs in food: repeat-dose (chronic) toxicity testing	ICH/VICH/468/2003	30/05/2005	Final
VICH GL54 Studies to evaluate the safety of veterinary drugs in human food: general approach to testing	ICH/VICH/632/2010	01/10/2017	Final
Assessment and control of residues of veterinary medicines in food of animal origin	EMA/CVMP/VICH/632/2010	01/10/2017	Guideline
Regulatory acceptance of veterinary medicines in food of animal origin	EMA/CVMP/VICH/632/2010	01/10/2017	Guideline

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## USER SAFETY

Name	Number	Effective from	Note
User safety for pharmaceuticals	EMA/CVMP/ERA/5142/2010	16/01/2010	Rev. 1
User safety of topically administered products	EMA/CVMP/ERA/721059/2014		Draft guideline

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## ENVIRONMENTAL RISK ASSESSMENT

Name	Number	Effective from	Note
VICH GL6 Environmental impact assessment (EIS) for medicinal products	CVMP/VICH/592/2009	07/2009	Guideline Phase I
VICH GL38 Environmental impact assessment for veterinary medicinal products	CVMP/VICH/396/2006	10/2006	Guideline
Environmental impact assessment of medicinal products in support of the VICH GLs	EMA/CVMP/ERA/1828/2005	2005	Reflection paper
Assessment of persistent, bioaccumulative and toxic (PBT) substances	EMA/CVMP/ERA/52740/2007	04/2007	Guideline
Authorisation of veterinary medicinal products containing (potential) persistent, bioaccumulative and toxic (PBT) substances	EMA/CVMP/ERA/4621/2015		Reflection paper
Determining the fate of veterinary medicinal products in the environment	EMA/CVMP/ERA/430323/2008	2008	Guideline
Higher tier testing to investigate the environmental fate of ectoparasiticide veterinary medicinal products	EMA/CVMP/ERA/87473/2021		Reflection paper
Plant testing strategy for veterinary medicinal products			
EMA/CVMP/ERA/689041/2015	2015	2017	Guideline
Assessing the environmental and human health risks of medicinal products in groundwater	EMA/CVMP/ERA/103555/2013	2013	Guideline
Poorly extractable and/or non-extractable substances	EMA/CVMP/ERA/343254/2014		Reflection paper
Risk-mitigation measures related to the environmental assessment of veterinary medicinal products	EMA/CVMP/ERA/409328/2015		Reflection paper
ERA - QaA document implementing the environmental impact assessment for veterinary medicinal products	EMA/CVMP/ERA/62074/2008	2008	QaA document
Antimicrobial resistance in the environment			
EMA/CVMP/ERA/632109/2014			
Reflection paper			
ERA-QaA document in support of the guideline on the assessment of persistent, bioaccumulative and toxic (PBT) substances	EMA/CVMP/ERA/593989/2019		QaA document
Interpretation of Article 13(7) of Regulation (EC) No 609/2006	EMA/CVMP/ERA/62042/2020		Reflection paper
Interpretation of Article 72 of Regulation (EC) No 2452/2021	EMA/CVMP/ERA/2452019/2021		Reflection paper
Criteria for determining if a substance is essential when considering the context of Article 37	EMA/CVMP/ERA/16512/2021		Reflection paper
Environmental risk assessment of ectoparasiticide veterinary medicinal products used in cats and dogs	EMA/CVMP/ERA/31905/2021		
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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	EMA/CVMP/038/1995/01	01/01/1997	Under revision
Updated application software: withdrawal time calculation for tissues	EMA/CVMP/473/1998/01	08/09/2000	web page EMA
Determination of withdrawal periods for milk	EMA/CVMP/542/2003	13/04/2005	Under revision
Updated application software: withdrawal time calculation for milk	EMA/CVMP/542/2003	13/04/2005	web page EMA
Injection-site residues	EMA/CVMP/542/2003	13/04/2005	-
Setting health based exposure limits for veterinary drugs in the manufacturing of different medicinal products	EMA/CVMP/542/2003	13/04/2005	Under revision
VICH GL46 studies to evaluate the pharmacokinetics of veterinary drugs in food-producing animals	EMA/CVMP/542/2003	13/04/2005	Under revision
VICH GL47 studies to evaluate the pharmacokinetics of veterinary drugs in food-producing animals	EMA/CVMP/542/2003	13/04/2005	Under revision
VICH GL48 studies to evaluate the pharmacokinetics of veterinary drugs in food-producing animals	EMA/CVMP/542/2003	13/04/2005	Under revision
VICH GL49 studies to evaluate the pharmacokinetics of veterinary drugs in food-producing animals	EMA/CVMP/542/2003	13/04/2005	Under revision
VICH GL56 studies to evaluate the pharmacokinetics of veterinary drugs in food-producing animals	EMA/CVMP/542/2003	13/04/2005	Under revision
VICH GL57 on studies to evaluate the pharmacokinetics of veterinary drugs in food-producing animals	EMA/CVMP/542/2003	13/04/2005	Under revision
Injection-site residues: Evaluation of the impact of different injection sites on residue levels	EMA/CVMP/542/2003	13/04/2005	Under revision
Introducing a review and update of the existing guidelines on residues studies	EMA/CVMP/542/2003	13/04/2005	Under revision

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### MAXIMUM RESIDUE LIMITS (MRL'S)

Name	Number	Effective from	Note
Approach to establish a pharmacological acceptable daily intake (ADI)	EMA/CVMP/355/2006/01	01/06/2006	-
Data to be provided in support of applications for MRLs	EMA/CVMP/355/2006/01	01/06/2006	Under revision
Risk-analysis approach for food of animal origin	EMA/CVMP/355/2006/01	01/06/2006	-
VICH GL36 Studies to evaluate the safety of veterinary drugs in human food: General approach	EMA/CVMP/355/2006/01	01/06/2006	Under revision
Assessment of bioavailability of animal origin	EMA/CVMP/355/2006/01	01/06/2006	Under revision
Consideration of adjuvants under Council Regulation (EEC) No 2377/90	EMA/CVMP/355/2006/01	01/06/2006	Under revision
New approach developed by the WHO for the assessment of food safety	EMA/CVMP/355/2006/01	01/06/2006	Under revision
Approaches on how to conduct MRL studies	EMA/CVMP/355/2006/01	01/06/2006	Under revision
Definition of substances capable of being used as food additives	EMA/CVMP/355/2006/01	01/06/2006	Under revision
Establishment of maximum residue limits for veterinary drugs in food of animal origin	EMA/CVMP/355/2006/01	01/06/2006	Under revision

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**AVAILABILITY (MINOR USES / MINOR SPECIES)**

Name	Number	Effective from	Note
Guideline on safety and residue evaluation of veterinary medicinal products	EMA/CVMP/SWP/6878/2005/Rev2016	18/12/2006	-
Note regarding CVMP guideline on data requirements for veterinary medicinal products intended for minor uses and/or minor species	EMA/CVMP/136672/2005/Rev2006	10/07/2006	-
Establishment of MRLs for salmonella and fin fish	EMA/CVMP/1530/97	01/01/1998	-
Position paper regarding availability of veterinary medicinal products - extrapolation of maximum residue limits	EMA/CVMP/457/03	10/02/2003	-

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**MULTIDISCIPLINARY**

Name	Number	Effective from	Note
Guideline on pharmaceuticals for minor uses	EMA/CVMP/23804/05	18/12/2006	-
Investigation of chiral active substances	EMA/CVMP/3561/91	01/10/1993	-

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