



Animal Medicines Australia  
ABN 76 116 848 344 | ACN 116 848 344  
18 National Circuit  
Barton ACT 2600, Australia  
P: +61 2 6257 9022  
[animalmedicinesaustralia.org.au](http://animalmedicinesaustralia.org.au)

10 March 2022

Codex Contact Point  
Department of Agriculture, Water and the Environment  
Attention: Charitha Adikari Arachchi

By email only: [codex.contact@awe.gov.au](mailto:codex.contact@awe.gov.au)

Dear Codex committee members,

**Re: Request for comments on proposed maximum residue limits for veterinary drugs extrapolated to one or more species**

Thank you for the opportunity to provide comments on proposed maximum residue limits (MRLs) for veterinary drugs extrapolated to one or more species.

Animal Medicines Australia (AMA) is the peak industry body representing the leaders of the animal medicines industry in Australia. Our members companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products to protect and treat animal illness, disease and injury, and support animal welfare across the livestock, equine and companion animal sectors. AMA members range from local businesses to the local divisions of global companies and includes companies who manufacture in Australia for global export markets. AMA members represent more than 90% of Australian sales of registered veterinary products.

In principle, AMA supports the extrapolation of MRLs where possible and when appropriate. Extrapolation provides a pragmatic, risk management approach to determining MRLs when relevant residues data may not be available, thereby increasing the availability of Codex MRLs for veterinary medicines to support trade.

The approach outlined builds on the evaluations performed by JECFA for the reference species and sets out the criteria which, when satisfied, support the conclusion that metabolism in the reference and concerned species is sufficiently similar to allow the reference species MRLs to be applied to the concerned species while maintaining protection of the consumer.

The use of an extrapolation approach is also consistent with the 3 R's principles to reduce, replace and refine the use of animals in scientific research, particularly the consideration of alternate scientific approaches that do not use animals.

The use of extrapolation can also facilitate the development of MRLs for veterinary drugs in certain species for which the absence of an MRL currently precludes its use.

AMA notes the results of the pilot for extrapolation of MRLs identified in Part D of the Priority List established by CCRVDF24 for a number of veterinary drugs and associated tissues, and does not oppose the resulting MRLs.

If we can provide any further information, please feel free to contact me.

Yours Sincerely,

Dr Charmian Bennett

Director Science and Policy

*(unsigned for electronic submission)*