

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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CL 2021/98-RVDF
December 2021

TO: Codex Contact Points
Contact Points of international organizations having observer status with Codex

FROM: Secretariat,
Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme

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

DEADLINE: **25 March 2022**

BACKGROUND

1. The 25th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF25, 2021) agreed¹ to forward the *Approach for the extrapolation of maximum residue limits for veterinary drugs to one or more species* to the Codex Alimentarius Commission for adoption and inclusion as Annex C to the *Risk Analysis Principle applied by CCRVDF*. The 44th Session of the Commission (CAC44, 2021) adopted² the Approach as proposed by CCRVDF25.
2. CCRVDF25 further agreed to request the Codex Secretariat to issue the proposed extrapolated MRLs for comments through a circular letter (CL).
3. As agreed by CCRVDF25, an electronic working group chaired by the European Union, and co-chaired by Costa Rica, will discuss the extrapolated MRLs taking into account the comments submitted in response to this CL, and prepare revised proposals for consideration by CCRVDF26.

REQUEST FOR COMMENTS

4. Codex members and observers are invited to provide comments on the proposals for MRLs extrapolation for the different combinations of veterinary drugs/tissues as presented in the Annex of this CL³.
5. In submitting comments, Codex members and observers are invited to take account of the information provided in the tables for the respective veterinary drug and associated tissues, as in the Annex, and the *Approach for the Extrapolation of MRLs for Veterinary Drugs to One or More Species* available in REP21/RVDF25, Appendix III.

GUIDANCE ON THE PROVISION OF COMMENTS

6. Comments should be submitted through the Codex Contact Points of Codex members and observers using the OCS.
7. Points of Codex members and observers may log into the OCS and access the document open for comments by selecting "Enter" in the "My reviews" page, available after login to the system.
8. Other OCS resources, including, [Frequently Asked Questions \(FAQs\)](#), as well as the user manual and short guide, can be found at: <http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>.
9. For questions on the OCS, please contact Codex-OCS@fao.org.

¹ REP21/RVDF25, para. 105 & Appendix III:
Working documents for CCRVDF25 including the report of its Session are available on the CCRVDF25 webpage at: <http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCRVDF&session=25>

² REP21/CAC44
Working documents for CAC44 including the report of its Session are available on the CAC44 webpage at: <https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CAC&session=44>

³ [Codex webpage/Circular Letters:](#)
<http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>
[Codex webpage/CCRVDF/Circular Letters:](#)
<https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCRVDF>

ANNEX**MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS EXTRAPOLATED TO ONE OR MORE SPECIES****1. Amoxicillin – proposed extrapolation to ruminants****For Information**

Which species have MRLs been established in?	Cattle (µg/kg)	Sheep (µg/kg)	Pig (µg/kg)	Finfish
Muscle	50	50	50	50**
Fat*	50	50	50	-
Liver	50	50	50	-
Kidney	50	50	50	-
Milk	4	4	-	-
Were the MRLs established on the basis of a full evaluation undertaken by JECFA?	Yes			
Is the marker residue the parent compound?	Yes			
What are the M:Ts	The JECFA report (WHO TRS 969(10)) establishes a microbiological ADI and indicates that the only microbiologically active residue is the parent substance. The M:T in all tissues and milk is therefore considered to be 1 in all species			
Can the MRLs be extrapolated to ruminants?	Yes, as the M:T is 1 in all commodities and, in addition, identical MRLs already exist in 2 ruminant species			

* Fat/skin for pigs

** This value applies to finfish fillet

For commentsAmoxicillin MRLs extrapolated to ruminants

Muscle 50 µg/kg:

Fat* 50 µg/kg:

Liver 50 µg/kg:

Kidney 50 µg/kg:

Milk 4 µg/kg:

* Fat/skin for pigs

2. Benzylpenicillin – proposed extrapolation to ruminants

For information

Which species have MRLs been established in?	Cattle (µg/kg)	Sheep (µg/kg)	Pig (µg/kg)
Muscle	50	50	50
Fat	-	-	-
Liver	50	50	50
Kidney	50	50	50
Milk	4	-	-
Were the MRLs established on the basis of a full evaluation undertaken by JECFA?	Yes		
Is the marker residue the parent compound?	Yes		
What are the M:Ts	The JECFA report (WHO TRS 799(10)) uses a M:T of 1 in all tissues and milk of all species		
Can the MRLs be extrapolated to ruminants?	Yes, as the M:T is 1 in all commodities and, in addition, identical MRLs already exist in 2 ruminant species		

For comments

Benzylpenicillin MRLs extrapolated to ruminants

Muscle 50 µg/kg:

Fat - :

Liver 50 µg/kg:

Kidney 50 µg/kg:

Milk 4 µg/kg:

3. Tetracyclines – proposed extrapolation to ruminants

For information

Which species have MRLs been established in?	Cattle (µg/kg)	Sheep (µg/kg)	Pigs (µg/kg)	Poultry (µg/kg)	Fish* (µg/kg)	Giant prawn* (µg/kg)
Muscle	200	200	200	200	200	200
Fat	-	-	-	-	-	-
Liver	600	600	600	600	-	-
Kidney	1200	1200	1200	1200	-	-
Milk	100	100	-	-	-	-
Eggs	-	-	-	400	-	-
Were the MRLs established on the basis of a full evaluation undertaken by JECFA?	Yes					
Is the marker residue the parent compound?	Yes					
What are the M:Ts	The JECFA report (WHO TRS 888(10)) uses a M:T of 1 in all tissues, milk and eggs					
Can the MRLs be extrapolated to ruminants?	Yes, as the M:T is 1 in all tissues, milk and eggs and, in addition, identical MRLs already exist in 2 related ruminant species					

* Applies only to oxytetracycline

For comments

Tetracyclines MRLs extrapolated to ruminants

Muscle 200 µg/kg:

Fat - :

Liver 600 µg/kg:

Kidney 1200 µg/kg:

Milk 100 µg/kg:

4. Cyhalothrin – proposed extrapolation to ruminants

For information

Which species have MRLs been established in?	Cattle (µg/kg)	Sheep (µg/kg)	Pigs (µg/kg)
Muscle	20	20	20
Fat	400	400	400
Liver	20	50	20
Kidney	20	20	20
Milk	30	-	-
Were the MRLs established on the basis of a full evaluation undertaken by JECFA?	Yes		
Is the marker residue the parent compound?	Yes		
What are the M:Ts	The JECFA report (WHO TRS 900(10) uses the same M:T values in all species (1 in muscle, fat and milk, 0.06 in liver and 0.2 in kidney)		
Can the MRLs be extrapolated to ruminants?	Yes, as the M:Ts established for cattle and sheep are identical, the more conservative set of MRLs (cattle) can be extrapolated to other ruminants. As the M:T for cattle milk is 1, the MRL can be extrapolated to milk of other ruminants		

For comments

Cyhalothrin MRLs extrapolated to ruminants

Muscle 20 µg/kg:

Fat 400 µg/kg:

Liver 20 µg/kg:

Kidney 20 µg/kg:

Milk 30 µg/kg:

5. Cypermethrin – proposed extrapolation to ruminants

For information

Which species have MRLs been established in?	Cattle (µg/kg)	Sheep (µg/kg)
Muscle	50	50
Fat	1000	1000
Liver	50	50
Kidney	50	50
Milk	100	-
Were the MRLs established on the basis of a full evaluation undertaken by JECFA?	Yes	
Is the marker residue the parent compound?	Yes	
What are the M:Ts	The JECFA reports use the following values: 0.3 in muscle, 0.8 in fat, 0.1 in liver, 0.05 in kidney (WHO TRS 911(10) and 1 in milk (TRS 925(10) The same values appear to have been used for cattle and sheep	
Can the MRLs be extrapolated to ruminants?	Yes, as the M:Ts established for cattle and sheep are identical and, in addition, identical MRLs already exist in 2 ruminant species. As the M:T for cattle milk is 1, the MRL can be extrapolated to milk of other ruminants	

For comments

Cypermethrin MRLs extrapolated to ruminants

Muscle 50 µg/kg:

Fat 1000 µg/kg:

Liver 50 µg/kg:

Kidney 50 µg/kg:

Milk 100 µg/kg:

6. Deltamethrin – proposed extrapolation to ruminants

For information

Which species have MRLs been established in?	Cattle (µg/kg)	Sheep (µg/kg)	Chicken (µg/kg)	Salmon (µg/kg)
Muscle	30	30	30	30
Fat	500	500	500	-
Liver	50	50	50	-
Kidney	50	50	50	-
Milk	30	-	-	-
Eggs	-	-	30	-
Were the MRLs established on the basis of a full evaluation undertaken by JECFA?	Yes			
Is the marker residue the parent compound?	Yes			
What are the M:Ts	The JECFA reports (WHO TRS 893 and 918(10)) use the following values: 0.6 in fat, 0.04 in liver, 0.03 in kidney and 1 in milk M:T for muscle not reported but equivalent values were applied in all species			
Can the MRLs be extrapolated to ruminants?	Yes, the MRLs for cattle and sheep tissues are identical and so can be extrapolated. While the MRL for milk has only been established in one species, the M:T used for milk was 1 and consequently the MRL can be extrapolated to milk of other ruminants			

For comments

Deltamethrin MRLs extrapolated to ruminants

Muscle 30 µg/kg:

Fat 500 µg/kg:

Liver 50 µg/kg:

Kidney 50 µg/kg:

Milk 30 µg/kg:

7. Moxidectin – proposed extrapolation to ruminants

For information

Which species have MRLs been established in?	Cattle (µg/kg)	Sheep (µg/kg)	Deer (µg/kg)
Muscle	20	50	20
Fat	500	500	500
Liver	100	100	100
Kidney	50	50	50
Milk	-	-	-
Were the MRLs established on the basis of a full evaluation undertaken by JECFA?	Yes		
Is the marker residue the parent compound?	Yes		
What are the M:Ts	The JECFA report (WHO TRS 888(10) uses the following values: 0.75 for fat, 0.4 for muscle, 0.4 for liver and kidney for all three species		
Can the MRLs be extrapolated to ruminants?	Yes, as the M:Ts are the same in all three species (identical MRLs were originally established for cattle, sheep and deer [TRS 864(10)] but the muscle MRL for sheep was subsequently raised following a new residue study in sheep with the M:T remaining unchanged)		

For comments

Moxidectin MRLs extrapolated to ruminants

Muscle 20 µg/kg:

Fat 500 µg/kg:

Liver 100 µg/kg:

Kidney 50 µg/kg:

Milk - :

8. Spectinomycin – proposed extrapolation to ruminants

For information

Which species have MRLs been established in?	Cattle (µg/kg)	Sheep (µg/kg)	Pig (µg/kg)	Chicken (µg/kg)
Muscle	500	500	500	500
Fat	2000	2000	2000	2000
Liver	2000	2000	2000	2000
Kidney	5000	5000	5000	5000
Milk	200	-	-	--
Eggs	-	-	-	2000
Were the MRLs established on the basis of a full evaluation undertaken by JECFA?	Yes			
Is the marker residue the parent compound?	Yes			
What are the M:Ts	The JECFA report (WHO TRS 888(10)) uses the following values: 0.25 for liver and 1 for all other tissues, milk and eggs in all species			
Can the MRLs be extrapolated to ruminants?	Yes, as the M:Ts are the same in all species and, in addition, identical MRLs already exist in 2 related ruminant species			

For comments

Spectinomycin MRLs extrapolated to ruminants

Muscle 500 µg/kg:

Fat 2000 µg/kg:

Liver 2000 µg/kg:

Kidney 5000 µg/kg:

Milk 200 µg/kg:

9. Levamisole – proposed extrapolation to ruminants

For information

Which species have MRLs been established in?	Cattle (µg/kg)	Sheep (µg/kg)	Pig (µg/kg)	Poultry (µg/kg)
Muscle	10	10	10	10
Fat	10	10	10	10
Liver	100	100	100	100
Kidney	10	10	10	10
Milk	-	-	-	-
Eggs	-	-	-	-
Were the MRLs established on the basis of a full evaluation undertaken by JECFA?	Yes			
Is the marker residue the parent compound?	Yes			
What are the M:Ts?	The JECFA report (WHO TRS 851(10) uses the following values: 0.024 for all tissues			
Can the MRLs be extrapolated to ruminants?	Yes, as the M:Ts are the same in all species and, in addition, identical MRLs already exist in 2 related ruminant species			

For comments

Levamisole MRLs extrapolated to ruminants

Muscle 10 µg/kg:

Fat 10 µg/kg:

Liver 100 µg/kg:

Kidney 10 µg/kg:

Milk - :

10. Tilmicosin – proposed extrapolation to ruminants

For information

Which species have MRLs been established in?	Cattle (µg/kg)	Sheep (µg/kg)	Pigs (µg/kg)	Chicken* (µg/kg)	Turkey* (µg/kg)
Muscle	100	100**	100	150	100
Fat	100	100	100	250	250
Liver	1000	1000	1500	2400	1400
Kidney	300	300	1000	300	1200
Milk	-	-	-	-	-
Eggs	-	-	-	-	-
Were the MRLs established on the basis of a full evaluation undertaken by JECFA?	Yes				
Is the marker residue the parent compound?	Yes				
What are the M:Ts?	The JECFA report (WHO TRS 876(10) uses the following values: 0.05 for cattle and sheep liver, 0.10 for sheep kidney, 0.25 for cattle kidney, 0.10 for cattle and sheep muscle and fat, 0.50 for pig liver and kidney, 0.10 for pig muscle and fat				
Can the MRLs be extrapolated to ruminants?	Yes, although there is a difference in the M:T for cattle and sheep kidney, the MRLs recommended for these 2 species were identical				

* The value for fat applies to skin/fat

** Value not shown in database, but it was in the recommendation from JECFA

For comments

Tilmicosin MRLs extrapolated to ruminants

Muscle 100 µg/kg:

Fat 100 µg/kg:

Liver 1000 µg/kg:

Kidney 300 µg/kg:

Milk - :

11. Deltamethrin – proposed extrapolation to finfish

For information

Which species have MRLs been established in?	Cattle (µg/kg)	Sheep (µg/kg)	Chicken (µg/kg)	Salmon (µg/kg)
Muscle	30	30	30	30
Fat	500	500	500	-
Liver	50	50	50	-
Kidney	50	50	50	-
Milk	30	-	-	-
Eggs	-	-	30	-
Were the MRLs established on the basis of a full evaluation undertaken by JECFA?	Yes			
Is the marker residue the parent compound?	Yes			
What are the M:Ts?	The JECFA report (WHO TRS 893(10) indicates that a M:T in muscle of salmon was not established. However, the concentrations of the marker residue and total residues were very low in muscle (of all species), with the MRL established based on twice the LoQ (From TRS 918(10): 0.04 for liver, 0.03 for kidney and 0.60 for fat)			
Can the MRLs be extrapolated to bony fish?	Yes, as residues in muscle of all species evaluated including salmon were very low (<LoQ) and do not make a significant addition to consumer exposure (Note that it was considered appropriate to extend the MRL for mammalian muscle to <i>Salmonidae</i> without metabolism data in this family)			

For comments

Deltamethrin MRL extrapolated to finfish

Muscle 30 µg/kg:

12. Flumequine – proposed extrapolation to finfish

For information

Which species have MRLs been established in?	Cattle (µg/kg)	Sheep (µg/kg)	Pigs (µg/kg)	Chicken (µg/kg)	Trout (µg/kg)
Muscle	500	500	500	500	500
Fat	1000	1000	1000	1000	-
Liver	500	500	500	500	-
Kidney	3000	3000	3000	3000	-
Milk	-	-	-	-	-
Eggs	-	-	-	-	-
Were the MRLs established on the basis of a full evaluation undertaken by JECFA?	Yes				
Is the marker residue the parent compound?	Yes				
What are the M:Ts?	<p>The JECFA report (WHO TRS 900(10) uses the following values:</p> <p>Cattle: muscle, kidney and fat: 0.79, liver: 0.17</p> <p>Sheep: muscle, kidney and fat: 0.4, liver: 0.06</p> <p>Pigs: muscle, kidney and fat: 0.59, liver:0.07</p> <p>Chickens: 0.82 in all tissues</p> <p>Trout: no measurable residues of flumequine metabolites, so most probably M:T = 1</p>				
Can the MRLs be extrapolated to bony fish?	Yes, as the M:T in trout is most probably 1 (suggesting no significant metabolism in fish) and, in addition, identical MRLs have been established in multiple unrelated species.				

For comments

Flumequine MRL extrapolated to finfish

Muscle 500 µg/kg: