

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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CL 2020/42-RVDF (Rev 1)

December 2020

**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 / INFORMATION ON**

- I. **The approach for the extrapolation of maximum residue limits for veterinary drugs to one or more species**
- II. **The proposals for MRLs based on the approach proposed for extrapolation of MRLs to one or more species**

**DEADLINE: 28 February 2021**

**COMMENTS: To:** CCRVDF Secretariat  
U.S. Codex Office  
Trade and Foreign Agricultural Affairs  
US Department of Agriculture  
E-mail: [CCRVDF-USSEC@usda.gov](mailto:CCRVDF-USSEC@usda.gov)

**Copy to:** Codex Secretariat  
Codex Alimentarius Commission  
Joint FAO/WHO Food Standards Programme  
E-mail: [codex@fao.org](mailto:codex@fao.org)

## BACKGROUND

1. See CX/RVDF 20/25/8<sup>1 2</sup>.
2. In order to focus comments on the relevant sections of the discussion paper<sup>3</sup> the proposed approach for the extrapolation of maximum residue limits for veterinary drugs to one or more species and the corresponding group MRLs extrapolated based on the proposed approach for the compounds identified in Part D of the Priority List agreed by CCRVDF24 are reproduced in Annexes I<sup>4</sup> and II<sup>5</sup> of this circular letter (CL) respectively.
3. The remaining sections<sup>6</sup> in the discussion paper, the revised Option C<sup>7</sup> and the compounds listed in Part D<sup>8</sup> of the Priority Lists remain as support information to provide comments on Annexes I and II of this CL.

## REQUEST FOR COMMENTS/INFORMATION

4. In view of the relocation of CCRVDF25 to 12-16 July 2021, the deadline for comments has been extended to give further opportunity to Codex members and observers to provide their comments in advance to CCRVDF25. Kindly note that, in view of the possibility that CCRVDF25 will be held in virtual mode, it is of upmost importance to submit comments well in advance to the plenary session, i.e. to reduce the number of conference room documents (CRDs) to the minimum possible, in order to facilitate the consideration of the approach and the MRLs at CCRVDF25.
5. Codex members and observers wishing to provide comments on Annexes I and II should send their proposals **by email, in word file**, to the above addresses and by the **deadline** indicated above.

<sup>1</sup> Working documents for CCRVDF25 are available on the CCRVDF25 webpage at:

<http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCRVDF&session=25>

<sup>2</sup> Circular letters are available on the Codex webpage/Circular Letters and can also be accessed from the CRVDF website (related circular letters): <http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en>  
<http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-meetings/en/?committee=CCRVDF>

<sup>3</sup> CX/PR 20/25/8, Appendix I

<sup>4</sup> CX/PR 20/25/8, Appendix I, Section II

<sup>5</sup> CX/PR 20/25/8, Appendix I, Section IV

<sup>6</sup> CX/PR 20/25/8, Appendix I, Sections I and III

<sup>7</sup> CX/PR 20/25/8, Appendix II

<sup>8</sup> CX/PR 20/25/8, Appendix III

**Annex I. The approach for the extrapolation of maximum residue limits for veterinary drugs to one or more species: CX/RVDF 20/25/8, Appendix I, Section II**

6. Codex members and observers are invited to consider the proposed approach and:
  - (i) To confirm the approach for the extrapolation of MRLs for veterinary drugs to one or more species as proposed in the discussion paper or
  - (ii) To provide their comments (including relevant information if appropriate) on the proposed approach as to e.g. further requirements that should be taken into consideration when deciding to extrapolate MRLs for veterinary drugs to one or more species; additional information that should be submitted for extrapolation of MRLs; any other considerations that Codex members and observers may find suitable to improve the aforesaid proposal.
7. In confirming or providing comments / information on the proposed approach, Codex members and observers are invited to take into consideration the conclusion and information provided in CX/RVDF 20/25/8, Appendix I, Sections I and III of the discussion paper, in particular the comparison between the approach proposed to extrapolate MRLs for veterinary drugs to one or more species and the approach proposed to extrapolate MRLs for veterinary drugs to aquatic species considered at CCRVDF24 (so-called "revised Option C").

**Annex II. The proposals for MRLs based on the approach proposed for extrapolation of MRLs for veterinary drugs to one or more species: CX/RVDF 20/25/8, Appendix I, Section IV**

8. Based on comments submitted on Annex I, Codex members and observers are invited to provide comments on the proposals for MRLs for veterinary drugs that have been extrapolated based on the approach proposed for the extrapolation of MRLs to one or more species and using the compounds identified by CCRVDF24 for this exercise which are described in Part D<sup>9</sup> of the Priority List of Veterinary Drugs.
9. Following the amendment of the Risk Analysis Principles applied by CCRVDF, risk managers (CCRVDF) can now propose MRLs based on extrapolation rules agreed by CCRVDF. Since such rules are those addressed in Annex I, the proposed MRLs are being circulated for comments at Step 3 and consideration by CCRVDF25 (2021) at Step 4 subject to confirmation of the approach by CCRVDF25 in order to proceed with the advancement of these MRLs in the Step Procedure.

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<sup>9</sup> REP18/RVDF, Appendix VI, Part D

**PROPOSED APPROACH FOR THE  
EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS OF VETERINARY DRUGS TO ONE OR MORE SPECIES  
(For comments)**

**Proposed approach<sup>10</sup>****General criteria for extrapolation**

1. Extrapolation should take place only between the same tissues/food commodities in the reference and concerned species (e.g. muscle to muscle, fat to fat etc.).
2. Extrapolation of reference species MRLs to a concerned species on a one to one basis should be considered only if **all** of the following are satisfied:
  1. the reference and concerned species are related.
  2. the marker residue in the reference species is the parent compound only or the MRL status in the reference species is 'unnecessary' and there is an expectation that the active substance will be used under the same conditions (i.e. by the same administration routes and at similar doses) in both species.
  3. the M:T established for the reference species can be applied to the concerned species.

**Specific criteria for extrapolation**

3. In order to ensure that the third of the above-mentioned three general criteria is satisfied, the following specific criteria are proposed.
  - (i) Where identical MRLs have been established in at least two related species on the basis of JECFA recommendations, these MRLs can be extrapolated to other related species (e.g. extrapolate from cattle and sheep to all ruminants).

**Explanatory note:** *The existence of identical MRLs in two related species provides grounds upon which to base the assumption that metabolism does not vary significantly within the group of related species—i.e. that the M:T established for the reference species can be applied to the concerned species.*
  - (ii) Where identical M:T values have been used in JECFA calculations for two related species but the MRLs recommended (by JECFA) differ, the most conservative set of MRLs (i.e. the MRLs from the species associated with the lowest consumer exposure estimate) can be extrapolated to other related species (e.g. where different MRL values have been established for cattle and sheep and extrapolation is considered to goats, the lowest set of MRLs should be used for extrapolation).

**Explanatory note:** *The fact that JECFA considered it appropriate to use identical M:T values in two related species provides grounds upon which to base the assumption that metabolism does not vary significantly within the group of related species—i.e. that the M:T established for the reference species can be applied to the concerned species.*
  - (iii) Where the M:T established by JECFA is 1 in all tissues in a single reference species, the same MRLs can be extrapolated to related species.

**Explanatory note:** *The fact that the M:T is 1 in all tissues/food commodities indicates that the substance is not metabolized to any significant degree. It is considered reasonable to assume that this would also be the case in the concerned species.*

Finally, while the above criteria can be used in all cases, the following additional criteria are proposed for fish, milk and eggs (i.e. extrapolation for fish, milk and eggs may be based on the above criteria OR based on the additional criteria below):

- (iv) For fish, where the MRL in muscle/fillet recommended by JECFA was established based on the limit of quantification (LoQ) (e.g., twice the LoQ), the MRL can be extrapolated to all bony fish.

**Explanatory note:** *The fact that the MRL in muscle/fillet is below the LoQ indicates that residues in muscle/fillet are not measurable and so do not make a significant contribution to the intake calculation. Even if there are differences in metabolism between fish species, the possibility that they will be so dramatic as to result in a level of residues in muscle/fillet sufficiently high to significantly impact on overall consumer exposure is considered unrealistic.*

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<sup>10</sup> CX/RVDF 20/25/8, Appendix I, Section II

- (v) For milk and eggs, where the M:T established by JECFA is 1 (in milk or eggs of a reference species), the milk/egg MRL of the reference species can be extrapolated to milk of other ruminants and eggs of other domesticated poultry species, respectively, even if the M:T is not 1 in tissues.

**Explanatory note:** For milk and eggs, there may be a concern that the fat content differs between related species. However, if the M:T is 1 in the reference species this indicates that the M:T is not significantly influenced by the fat content.

#### Reporting extrapolated MRLs

4. Where CCRVDF agrees to extrapolate MRLs, it should be clear that these MRLs were established by extrapolation rather than on the basis of a substance/species specific JECFA assessment. An appropriate symbol should be included next the relevant values reported in the Codex MRL database. Moreover, extrapolated MRLs should be reconsidered in case the reference MRLs are modified or new data/information on the active substance in question becomes available.

#### Table summarizing proposed MRL extrapolations

From reference species	To concerned species
Tissues of a ruminant (e.g. cattle, sheep, goats)	Tissues of all ruminants if the marker residue is the parent only* and one of the following apply: <ul style="list-style-type: none"> <li>(i) identical MRLs already exist in 2 ruminant species</li> <li>(ii) identical M:Ts exist in 2 ruminant species</li> <li>(iii) MRLs have been established in only 1 ruminant species but the M:T = 1 in all tissues.</li> </ul>
Milk of a ruminant (e.g. cattle, goats)	Milk of all ruminants if the marker residue is the parent only* and one of the following apply: <ul style="list-style-type: none"> <li>(i) identical MRLs already exist in milk of 2 ruminant species</li> <li>(ii) identical M:Ts exist in milk of 2 ruminant species</li> <li>(iii) a milk MRL has been established in only 1 ruminant species and the M:T = 1 in milk.</li> </ul>
Tissues of a non-ruminant mammal (e.g. pigs)	Tissues of all non-ruminant mammals if the marker residue is the parent only* and one of the following apply: <ul style="list-style-type: none"> <li>(i) Identical MRLs already exist in 2 non-ruminant mammal species.</li> <li>(ii) Identical M:Ts exist in 2 non-ruminant mammal species.</li> <li>(iii) MRLs have been established in only 1 non-ruminant species but the M:T = 1 in all tissues.</li> </ul>
Tissues of a bird (e.g. chickens)	Tissues of all birds if the marker residue is the parent only* and one of the following apply: <ul style="list-style-type: none"> <li>(i) Identical MRLs already exist in 2 bird species.</li> <li>(ii) Identical M:Ts exist in 2 bird species.</li> <li>(iii) MRLs have been established in only 1 species but the M:T = 1 in all tissues.</li> </ul>

From reference species	To concerned species
Eggs from a bird (e.g. chickens)	Eggs from all birds if the marker residue is the parent only* and one of the following apply: <ul style="list-style-type: none"> <li>(i) Identical MRLs already exist in eggs of 2 bird species.</li> <li>(ii) Identical M:Ts exist in eggs of 2 bird species.</li> <li>(iii) MRLs have been established in only 1 bird species but the M:T = 1 in eggs.</li> </ul>
Muscle/fillet of a bony fish (e.g. salmon)	Muscle/fillet of all bony fish if the marker residue is the parent only* and one of the following apply: <ul style="list-style-type: none"> <li>(i) Identical MRLs already exist in muscle/fillet of 2 bony fish species.</li> <li>(ii) Identical M:Ts exist in muscle/fillet of 2 bony fish species.</li> <li>(iii) MRLs have been established in only 1 fish species but the M:T = 1 in the reference species.</li> <li>(iv) The MRL in the reference species was established based on twice the LoQ.</li> </ul>

\*The requirement that the marker residue is the parent only does not apply in cases where the MRL classification is 'unnecessary' as there is no marker residue in these cases.

**ANNEX II**

**MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS EXTRAPOLATED TO ONE OR MORE SPECIES**  
**(Based on the approach<sup>11</sup> described in Annex II**  
**and using compounds as identified in Part D of the Priority List<sup>12</sup> of Veterinary Drugs)**  
**(For comments at Step 3)**

<b>1. Amoxicillin – proposed extrapolation to ruminants</b>					
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				
If so, what MRLs are proposed?	Muscle	50 µg/kg			
	Fat*	50 µg/kg			
	Liver	50 µg/kg			
	Kidney	50 µg/kg			
	Milk	4 µg/kg			

\* Fat/skin for pigs

\*\* This value applies to finfish fillet

<sup>11</sup> CX/RVDF 20/25/8, Appendix I, Section II

<sup>12</sup> REP18/RVDF, Appendix VI, Part D

2. Benzylpenicillin – proposed extrapolation to ruminants				
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			
If so, what MRLs are proposed?	Muscle	50 µg/kg		
	Fat	-		
	Liver	50 µg/kg		
	Kidney	50 µg/kg		
	Milk	4 µg/kg		

3. Tetracyclines – proposed extrapolation to ruminants							
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						
If so, what MRLs are proposed?	Muscle	200 µg/kg					
	Fat	-					
	Liver	600 µg/kg					
	Kidney	1200 µg/kg					
	Milk	100 µg/kg					

\* Applies only to oxytetracycline



4. Cyhalothrin – proposed extrapolation to ruminants				
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			
If so, what MRLs are proposed?	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			
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		
If so, what MRLs are proposed?	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					
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				
If so, what MRLs are proposed?	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				
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)			
If so, what MRLs are proposed?	Muscle	20 µg/kg		
	Fat	500 µg/kg		
	Liver	100 µg/kg		
	Kidney	50 µg/kg		
	Milk	-		

8. Spectinomycin – proposed extrapolation to ruminants					
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				
If so, what MRLs are proposed?	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					
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				
If so, what MRLs are proposed?	Muscle	10 µg/kg			
	Fat	10 µg/kg			
	Liver	100 µg/kg			
	Kidney	10 µg/kg			
	Milk	-			

10. Tilimicosin – proposed extrapolation to ruminants						
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					
If so, what MRLs are proposed?	Muscle	100 µg/kg				
	Fat	100 µg/kg				
	Liver	1000 µg/kg				
	Kidney	300 µg/kg				
	Milk	-				

\* The value for fat applies to skin/fat

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

11. Deltamethrin – proposed extrapolation to bony fish					
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?	<p>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</p> <p>(From TRS 918(10): 0.04 for liver, 0.03 for kidney and 0.60 for fat)</p>				
Can the MRLs be extrapolated to bony fish?	<p>Yes, as residues in muscle of all species evaluated including salmon were very low (&lt;LoQ) and do not make a significant addition to consumer exposure</p> <p>(Note that it was considered appropriate to extend the MRL for mammalian muscle to <i>Salmonidae</i> without metabolism data in this family)</p>				
If so, what MRLs are proposed?	Muscle	30 µg/kg			



12. Flumequine – proposed extrapolation to bony fish						
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.					
If so, what MRLs are proposed?	Muscle	500 µg/kg				

13. Teflubenzuron – proposed extrapolation to bony fish		
Which species have MRLs been established in?		Salmon (µg/kg)
	Muscle	400
	Fillet*	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 997(10) uses 0.8 for both muscle and fillet	
Can the MRLs be extrapolated to bony fish?	No, as the M:T is not 1 (i.e. there is metabolism) and as the MRLs are not based on the LoQ (indicating that residues make a significant contribution to the overall consumer intake)	

\* Muscle and skin in natural proportions