

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda item 7.1

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**  
**Twenty-eighth Session**  
**23–27 March 2026**

**Minneapolis, Minnesota, United States of America**

**EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS OF VETERINARY DRUGS IN FOODS TO ONE OR MORE SPECIES**  
**EXTRAPOLATION OF MRLs FOR CAMELIDS IN VARIOUS TISSUES:**  
**Albendazole, Ivermectin, and Oxytetracycline**

**(At Step 4)**

(Prepared by the Electronic Working Group chaired by  
the United Kingdom of Great Britain and Northern Ireland and co-chaired by Costa Rica)

Codex members and observers wishing to submit comments on the extrapolated MRLs for camelids in various tissues, as presented in Appendix I, should do so as instructed in CL 2026/11-RVDF available on the Codex webpage/Circular Letters<sup>1</sup> or CCRVDF/Related Circular Letters<sup>2</sup>

## INTRODUCTION

1. The 27<sup>th</sup> Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF27, 2024) established the Electronic Working Group (EWG) on Extrapolation to consider Codex Members' requests relating to the extrapolation of MRLs for veterinary drugs.
2. There were two streams of work included in the Terms of Reference (ToR).
3. The first workstream was to establish criteria to enable the extrapolation of established maximum residue limits (MRLs) to 'other edible offals'.
4. The second workstream was to consider Codex Members' requests for extrapolation of established MRLs to additional species, in line with established criteria, which had been added to Part V of the Priority List.
5. This is the report for the second workstream.

## TERMS OF REFERENCE (ToRs)

6. The EWG should<sup>3</sup>:
  - Consider any nominations for extrapolations that may be received under Part V of the priority list using the established extrapolation criteria.
  - The EWG may consider proposing enhancements to the criteria as appropriate.

## WORK PROCESS: PARTICIPATION AND METHODOLOGY

7. Thirty-five Codex Members and two Observers registered to participate in the EWG. The list of participants is attached in Appendix III.
8. The EWG Chairs circulated the first message to the participants on 18<sup>th</sup> March 2025 in English and Spanish.

<sup>1</sup> <http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

<sup>2</sup> <http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCRVDF>

<sup>3</sup> [REP24/RVDF17](#), paras 90 (ii), 133, Appendix VII, Part V

9. An introductory document explained the Chair's understanding of the work to be undertaken and outlined specific tasks to be addressed. Two rounds of comments from EWG members followed, followed by a summary of the work undertaken and conclusions/recommendations, which are provided below. The detailed documents and comments circulated within the EWG are available in Appendix II for information.

#### EXTRAPOLATION OF MRLS RECEIVED UNDER PART V OF THE PRIORITY LIST OF VETERINARY DRUGS

10. The following substances were added to Part V of the priority list<sup>4</sup> for extrapolation:

Compound	Extrapolation to
Albendazole	Camelids (tissues and milk)
Ivermectin	Camelids (tissues and milk)
Oxytetracycline	Camelids (tissues and milk)

#### THE CRITERIA ESTABLISHED BY CCRVDF27 FOR EXTRAPOLATION TO CAMELIDS

11. For camelids, extrapolation of MRLs can be supported where the following criteria are satisfied:
- 1) Extrapolation should only occur between the same tissues/food commodities in the reference and concerned species (e.g., muscle to muscle, fat to fat, etc.).
  - 2) The marker residue is the parent compound.
    - In cases where the active substance is a combination of homologous compounds, the marker residue can be considered the same as the parent if it is a homolog that is a major component of the active substance.
  - 3) For meat tissues, extrapolation of reference species MRLs to camelids on a one-to-one basis should be considered if either:
    - identical MRLs have been established in at least one ruminant species and one non-ruminant mammalian species based on the recommendations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and the M:T ratio used by JECFA was 1 in all tissues for the ruminant and nonruminant species, OR
    - based on JECFA recommendations, identical MRLs have been established in at least one ruminant, non-ruminant mammalian, and avian species. JECFA used the same M:T ratio for each tissue type for all three species.
  - 4) Where conditions 2 and 3 are satisfied, extrapolation of an MRL for milk should also be considered in those cases where the M:T ratio used by JECFA was 1 in milk.
12. The determination of whether the requested substances meet the criteria is in Appendix I.
- Albendazole:**
13. There is agreement amongst the EWG respondents that the proposed extrapolation of established albendazole MRLs to camelids **does not meet the criteria** established by CCRVDF. Therefore, extrapolation of albendazole to camelids is **not recommended** by the EWG.
- Ivermectin:**
14. There is agreement amongst the EWG respondents that the proposed extrapolation of established ivermectin MRLs to camelids **does not meet the criteria** established by CCRVDF. Therefore, extrapolation of ivermectin to camelids is **not recommended** by the EWG.
- Oxytetracycline:**
15. For oxytetracycline, there was consensus amongst the respondents that this substance **does meet the criteria** and so **can be extrapolated** to camelids (tissues and milk), based upon the criteria established by CCRVDF.

<sup>4</sup> [REP24/CAC47](#), para 169, Appendix V

16. In addition, since the entry in the *Maximum residue limits and risk management recommendations for residues of veterinary drugs in foods* (CXM 2) covers all tetracyclines (tetracycline and chlortetracycline, as well as oxytetracycline), and includes all three in the ADI and as marker residues, the EWG will recommend that all three of these substances are extrapolated to camelids, as all the criteria are met for these substances, and to remove the need to separate their entries (although it is noted that the established fish and giant prawn MRLs apply only to oxytetracycline).
17. **Note:** As tetracycline and chlortetracycline had not been added to the priority list, there is a possibility that CCRVDF will not accept the recommendation to extrapolate their MRLs to camelids. In this case, it will be recommended that CCRVDF add them to Part V of the Priority List, for extrapolation at the earliest opportunity.

#### **SUMMARY OF KEY POINTS OF DISCUSSION**

18. The Chair asked the participants to consider whether any of the established criteria for extrapolation of MRLs to camelids could or should be modified to enable substances such as ivermectin, which is used in many different species globally, to be extrapolated to camelids. However, there was consensus amongst respondents that amending the criteria should not be proposed to the CCRVDF. This was due to there not being any reasonable amendments that could be made that would allow the extrapolation of established ivermectin MRLs to camelids.
19. One member has raised the point that the composition of milk can be quite different between species. The concern relates to lipid-soluble compounds that may partition into the milk fats. However, extrapolation of MRLs to other species is an approach that requires no additional data other than those which JECFA and CCRVDF have published or are otherwise available publicly. It is risk-based and cannot be perfect in all cases. A concern was that the extrapolation of MRLs may lead to extended withdrawal periods for some species' food commodities, such as milk; however, when the established criteria for extrapolation are met, the process will ensure consumer safety and allow for smoother trade between Members. The length of withdrawal period(s) cannot be a criterion for extrapolation, as additional data would need to be provided, and setting withdrawal periods would be a local authority competence. For species-specific MRLs to be established, the relevant data should be provided to JECFA for assessment.

#### **CONCLUSION**

20. The EWG fulfilled its mandate as outlined in its ToRs. The results of its work are detailed in Appendix I. For additional context, Appendix II provides a summary of the EWG's discussions, including comments and responses from the EWG Chair. This supplementary information offers valuable insights that help clarify the process and rationale behind the extrapolation of maximum residue limits (MRLs) for camelids, as described in Appendix I.

#### **RECOMMENDATIONS**

21. Codex members and observers are invited to consider:
  - i. The recommendations for extrapolation of MRLs for camelids in various tissues as presented in Appendix I, based on the considerations provided in paragraphs 13-17 of this document, for comments and consideration by CCRVDF28.

**APPENDIX I****EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS OF VETERINARY DRUGS FOR CAMELIDS IN VARIOUS TISSUES:  
Albendazole, Ivermectin, and Oxytetracycline****(For comments at Step 3)****RECOMMENDATION 1: Extrapolating MRLs for albendazole to camelids.**

- 1.1 Extrapolation of the MRLs established for albendazole in the edible tissues and milk of cattle and sheep to camelids is not supported.

ALBENDAZOLE	Existing MRLs	
		Cattle & Sheep (µg/kg)
Commodity	Muscle	100
	Liver	5000
	Kidney	5000
	Fat	100
	Milk	100
Is the marker residue the parent compound?	No. The marker residue is 2-amino-benzimidazole, a metabolite of albendazole common to cattle, sheep, rats, and mice. To calculate the total residues in liver, the concentration of the marker residue is multiplied by 5 for cattle and 6 for sheep. It is not clear how the MRLs for the other edible tissues were established from the information available, or whether the same calculations should be made for each edible tissue.	
Have identical MRLs been established in at least one ruminant species and one non-ruminant mammalian species based on JECFA recommendations?	This is not clear – the JECFA report (see <a href="#">Veterinary Drug Detail   CODEXALIMENTARIUS FAO-WHO</a> ) focuses on cattle and sheep, but the website has ‘not specified’ in the species column. The extrapolation page ( <a href="#">Extrapolated MRLs   CODEXALIMENTARIUS FAO-WHO</a> ) does not mention albendazole. It is therefore assumed that only cattle and sheep have established MRLs.	
Did JECFA use an M:T of 1 in both species?	No. The M:T in cattle liver is 0.2; the M:T in sheep liver is 0.17. The M:Ts in the other edible tissues have not been described in the available information.	
Have identical MRLs been established in at least one ruminant, one non-ruminant mammalian species, and an avian species?	No, no data appear to be available for species other than cattle and sheep (both ruminants).	
Did JECFA use the same M:T for each tissue type for all three species?	Not applicable (see above).	
Can the MRLs be extrapolated to camelids?	No.	
Proposed MRLs:	None are proposed.	

**RECOMMENDATION 2: Extrapolating MRLs for ivermectin to camelids.**

2.1 Extrapolation of the MRLs established for ivermectin in the edible tissues of cattle, sheep, goats, and pigs, and the milk of cattle and sheep, to camelids is not supported.

IVERMECTIN	Existing MRLs			
		Cattle (µg/kg)	Sheep and goats (µg/kg)	Pigs (µg/kg)
Commodity	Muscle	30	30	15
	Liver	800	60	30
	Kidney	100	20	20
	Fat	400	100	50
	Milk	10	Not established	Not established
Is the marker residue the parent compound?	Yes (in cases where the active substance is a combination of homologous compounds, the marker residue can be considered the same as the parent if it is a homolog that is a major component of the active substance).			
Have identical MRLs been established in at least one ruminant species and one non-ruminant mammalian species based on JECFA recommendations?	No. The MRLs for cattle are not the same as for sheep/goats and neither are the same as those for pigs.			
Did JECFA use an M:T of 1 in both species?	Not applicable, since the MRLs are not the same.			
Have identical MRLs been established in at least one ruminant, one non-ruminant mammalian species, and an avian species?	No. The MRLs for cattle are not the same as for sheep/goats and neither are the same as those for pigs. There are no MRLs established for avian species.			
Did JECFA use the same M:T for each tissue type for all three species?	Not applicable, since the MRLs are not the same.			
Can the MRLs be extrapolated to camelids?	No.			
Proposed MRLs:	None are proposed.			

**RECOMMENDATION 3: Extrapolating MRLs for oxytetracycline to camelids.**

- 3.1 The MRLs established for oxytetracycline in the edible tissues of cattle, sheep, pigs, and poultry, and the milk of cattle and sheep, can be extrapolated to camelids.
- 3.2 With agreement on Recommendation 3.1, the MRLs established for tetracycline and chlortetracycline in the tissues of cattle, sheep, pigs, and poultry, and the milk of cattle and sheep, can be extrapolated to camelids.

OXYTETRACYCLINE	Existing MRLs	
		Cattle, Sheep, pigs and poultry (µg/kg)
Commodity	Muscle	200
	Liver	600
	Kidney	1200
	Fat	Not established
	Milk (cattle and sheep)	100
Is the marker residue the parent compound?	Yes. The marker residue is the sum of tetracycline, oxytetracycline, and chlortetracycline.	
Have identical MRLs been established in at least one ruminant species and one non-ruminant mammalian species based on JECFA recommendations?	Yes.	
Did JECFA use an M:T of 1 in both species?	Yes.	
Have identical MRLs been established in at least one ruminant, one non-ruminant mammalian species, and an avian species?	Yes.	
Did JECFA use the same M:T for each tissue type for all three species?	Yes.	
Can the MRLs be extrapolated to camelids?	Yes.	
Proposed MRLs*:	Muscle	200 µg/kg
	Liver	600 µg/kg
	Kidney	1200 µg/kg
	Milk	100 µg/kg

\* Since the same criteria are also met for both tetracycline and chlortetracycline (and the marker residue is the sum of all three compounds), it is additionally recommended that the MRLs established for tetracycline and chlortetracycline are extrapolated to camelids (edible tissues and milk).

**APPENDIX II****Circulated documents and comments from participants, including comments and replies from the EWG Chair during the discussions in the EWG****(For information)****Round 1:****First list of questions for the EWG:**

1. Do you agree with the draft evaluations above and their conclusions?
2. Can you propose any further criteria, or changes to the currently agreed criteria, that might allow the extrapolation of ivermectin to camelids, whilst ensuring consumer safety?

	<b>Responses</b>				
<b>Member State or Organisation</b>	<b>Brazil</b>	<b>European Union</b>	<b>Kingdom of Saudi Arabia</b>	<b>United States of America</b>	<b>New Zealand</b>
<b>Questions:</b>					
<b>Do you agree with the draft evaluations and their conclusions?</b>	Yes, Brazil agrees with the draft evaluations and conclusions.	The conclusions as presented by the chairs are supported. In relation to albendazole, the JECFA secretariat could be asked to clarify how the species 'not specified' should be interpreted.	Yes, Saudi Arabia agrees with the draft evaluations and their conclusions for both Albendazole and Ivermectin. The conclusion that albendazole does not meet the criteria for extrapolation is appropriate. The marker residue is not the parent compound, and the M:T ratios differ between species. Furthermore, data are limited to ruminants, and the necessary cross-species consistency is not established. The conclusion that ivermectin cannot currently be extrapolated to camelids is justified.	The United States agrees that albendazole does not meet the extrapolation criteria set by CCRVDF, and so the existing MRLs cannot be extrapolated to camelids. The United States agrees that ivermectin does not meet the extrapolation criteria set by CCRVDF, and so the existing MRLs cannot be extrapolated to camelids. The United States agrees that oxytetracycline meets all criteria set by CCRVDF for MRL extrapolation to camelid edible tissues and milk. The United States agrees with the draft recommendation to extrapolate the oxytetracycline MRLs for cattle, sheep, pig and poultry to camelid species.	Yes in general, though a comment for extrapolation with respect to milk: Has there been any consideration of the impact of milk composition when extrapolating milk MRLs, particularly where the compound is fat soluble and therefore likely to be partitioned in milk fats?

	Responses				
Member State or Organisation	Brazil	European Union	Kingdom of Saudi Arabia	United States of America	New Zealand
Questions:					
			<p>Despite the marker residue being the parent compound, the MRLs differ substantially between ruminant and non-ruminant species, and no consistent M:T ratios are evident across species. No avian data exist to further support extrapolation, and disagree with the conclusion of Oxytetracycline, may need take into consideration the withdrawal period in Camelids.</p>	<p>The United States also agrees, in principle, with the draft recommendation to extrapolate the tetracycline and chlortetracycline MRLs for cattle, sheep, pig and poultry to camelid species but seeks clarification on whether this can be done at this time, as these specific compounds were not added to Part V of the Priority List.</p> <p>In support of the proposed extrapolation, it is worth noting that, within CXM 2 , the MRL entry is listed as CHLORTETRACYCLINE/OXYTETRACYCLINE/TETRACYCLINE, and as noted by the eWG Chair and co Chair, the marker residue is sum of all three compounds. Therefore, a justification could be made that, by including oxytetracycline on the priority list, CCRVDF included chlortetracycline and tetracycline by default.</p>	<p>Some minor species have considerably different milk composition profiles compared to cattle, so extrapolation of fat soluble compounds may pose a risk of under- or over-estimation of milk residues in other species.</p>

	Responses				
Member State or Organisation	Brazil	European Union	Kingdom of Saudi Arabia	United States of America	New Zealand
Questions:					
Can you propose any further criteria, or changes to the currently agreed criteria, that might allow the extrapolation of ivermectin to camelids, whilst ensuring consumer safety?	No further comments.	Consideration could be given to extrapolating the most conservative set of MRLs which, in this case would be those established for pigs. These can be expected to be safe values, because although less than 1, M:T for ivermectin is rather similar across mammalian species. The disadvantage of this approach would be that it may lead to the need to establish long withdrawal periods.	No response given.	None at this time.	For point 2, the marker residue being the parent compound: the marker residue should be set to that established for species from which data is being extrapolated, not default to the parent compound. Using the albendazole example in the paper, 2-amino-benzimidazole is common to cattle, sheep, rats, and mice. It would follow then that extrapolation to goats would attract the same metabolite as the marker residue, rather than parent albendazole. It would make sense that if the data is representative enough to extrapolate to the additional species/commodity, the common residue definition should be too.

**Discussion:*****Albendazole:***

There is agreement amongst the EWG respondents that the proposed extrapolation of albendazole MRLs to camelids does not meet the criteria established by CCRVDF. Therefore, extrapolation of albendazole to camelids is not recommended by the EWG at this time.

One Member suggested that the EWG could ask the JECFA secretariat to clarify how the species 'not specified' should be interpreted.

The Chair did contact the JECFA secretariat on this point. In the JECFA vet drugs database it is indicated that the MRLs were recommended for cattle and sheep (<https://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-vetdrugs/details/en/c/5/>). The JECFA report <https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/478> was also investigated, and it also refers to cattle and sheep only.

The Chair also contacted the CODEX Secretariat for any further information on this.

If, as looks likely, the 'not specified' entry is an error, and the entry should read 'cattle and sheep', then albendazole does not meet the criteria for extrapolation. If CCRVDF have previously determined that the entry should be for all food-producing species, unlikely as this scenario may be, then this would already include camelids, and no extrapolation would be necessary.

One Member proposed that criterion number 2 (that the marker residue is the parent compound), could be amended so that if there were common metabolites used as the marker residue in all the species from which the MRLs were being extrapolated, then the same marker residues could be used for the species to which the MRLs were being extrapolated.

**Chair's comment:**

Most drug substances have common metabolites between species; however, it is the relative proportion of these metabolites that are considered when establishing MRLs. When the proportions change (M:T), so the MRLs change, which is why not all substances have the same MRLs for all species. As can be seen for albendazole, the M:Ts are different for cattle and sheep. This indicates that there is variability of pharmacokinetics between species, and so it is less likely that the species to which the MRLs are being extrapolated would have the same proportions of metabolites and parent substance (since those species from which the MRLs are being extrapolated do not between themselves). The criteria for extrapolation have been established to ensure that CCRVDF can be reasonably sure that using the same MRLs for other species would not change the consumer safety profile of the residues found in foods of animal origin sourced from treated animals.

Additionally, there are scientifically justified criteria for when the toxicology of metabolites needs to be assessed by JECFA. Not all metabolites are evaluated, only those with higher relative concentrations in tissues. So, if a new species has different pharmacokinetics for a substance, higher levels of metabolites with unknown toxicity may be formed and may lead to an unknown risk to consumer safety.

It is also noted that there is a lack of information available on the M:T for albendazole in tissues other than liver.

***Ivermectin:***

There is agreement amongst the EWG respondents that the proposed extrapolation of ivermectin MRLs to camelids does not meet the criteria established by CCRVDF. Therefore, extrapolation of ivermectin to camelids is not recommended by the EWG.

As there are so many different MRLs established for ivermectin, the Chairs of the EWG asked EWG members to consider whether there were any further criteria that may be considered that may allow for extrapolation of ivermectin MRLs to camelids.

One Member suggested that the most conservative MRLs established could be extrapolated to camelids, which would ensure consumer safety and allow for international trade in camelid-derived foods, but this did raise concerns over the potential length of Withdrawal Periods (WPs) that would be necessary to conform with those MRLs. This proposal should form part of a discussion within the EWG (see second list of questions for the EWG later in this document).

**Chair's comment:**

Extrapolation of MRLs from species with established MRLs to those without established MRLs is a risk-based approach to establishing MRLs for species for which there are less data available to JECFA/CCRVDF. The criteria for extrapolation should be robust, consistent, and easy to implement with the information available to CCRVDF. Although extrapolation of the lowest, most conservative MRLs to camelids in the case of ivermectin may ensure consumer safety, it may cause concerns over trade.

The principle of the established criteria is to allow extrapolation where there is very little difference in the pharmacokinetics between species, giving assurance that the species being extrapolated to would likely impart a similar risk for consumers to those already-established species. The wide variety of established MRLs for ivermectin indicates that there may be a high variability between species in pharmacokinetic parameters.

**Oxytetracycline:**

For oxytetracycline, all but one of the respondents agreed that this substance can be extrapolated to camelids, based on the criteria established by CCRVDF.

For the Member that did not agree, there was a concern that the withdrawal periods based on these MRLs might not be practicable. It should be noted that the length of withdrawal period is not one of the established criteria for extrapolation of MRLs, and in order to establish what the length of the WP might be, data from residue studies in camelids would need to be made available to JECFA/CCRVDF for evaluation.

The chair's proposal to recommend tetracycline and oxytetracycline to be included in the extrapolation, due to the common entry, MRLs, and marker residues, has generally been supported; however, there is the question of process, as highlighted by one Member of the EWG. Since these substances were not included in Part V of the Priority List, it may be that this proposal cannot be enacted at this time, and it would have to wait for an official nomination from a CCRVDF Member. Nonetheless, the Chair proposes that the EWG recommends all three tetracyclines for extrapolation to camelids, and CCRVDF can make the decision as to whether to accept this recommendation.

**Chair's comment on milk and withdrawal periods in species to which MRLs are extrapolated:**

One member has raised the point that the composition of milk can be quite different between species. This is certainly the case in terms of proportions of fats in milks. The concern relates to lipid-soluble compounds that may partition into the milk fats. Extrapolation of MRLs to other species is an approach that requires no additional data other than those which JECFA and CCRVDF have published. It is risk-based and cannot be perfect in all cases. It may lead to extended withdrawal periods for some species' food commodities, such as milk, but it will, when the established criteria for extrapolation are met, ensure consumer safety and allow for easier trade between Members. The length of the resultant withdrawal period(s) cannot be a criterion for extrapolation, as additional data would need to be provided. For species-specific MRLs to be established, JECFA requires the relevant data to be provided for them to conduct an assessment.

**Current position of the EWG:**

1. Extrapolation of albendazole and ivermectin MRLs to camelids cannot be recommended to CCRVDF based on the current criteria.
2. There is general consensus that oxytetracycline meets all the established criteria for extrapolation of MRLs to camelids. The recommendation to CCRVDF will include tetracycline and chlortetracycline. All three substances are currently grouped together in one listing and would all meet the established criteria for extrapolation.
3. There may be a need to amend some criteria to allow for extrapolation of more MRLs to camelids, whilst ensuring consumer safety.

**Second list of questions to the EWG:**

- 1) Do you agree that the Chair has accurately reflected the current position of the EWG?
- 2) It has been proposed, that when there are no common MRLs between species already established, such as in the case of ivermectin, that the EWG could recommend to CCRVDF that the MRLs from the species with the most conservative established MRLs (i.e., the lowest) be extrapolated to camelids.
  - a. Can you agree that this change to criterion 3 would be appropriate for both consumer safety and for trade purposes?
  - b. If you agree, are there any caveats that should be included (e.g., if the most conservative MRLs are in avian species, would this be relevant to camelids?).
- 3) Do you have any other comments or proposals on any of the points discussed above?

**Round 2:**

<p><b>Question 1:</b> Do you agree that the Chair has accurately reflected the current position of the EWG?</p> <ol style="list-style-type: none"> <li>1. Extrapolation of albendazole and ivermectin MRLs to camelids cannot be recommended to CCRVDF based on the current criteria.</li> <li>2. There is general consensus that oxytetracycline meets all the established criteria for extrapolation of MRLs to camelids. The recommendation to CCRVDF will include tetracycline and chlortetracycline. All three substances are currently grouped together in one listing and would all meet the established criteria for extrapolation.</li> <li>3. There may be a need to amend some criteria to allow for extrapolation of more MRLs to camelids, whilst ensuring consumer safety.</li> </ol>		
Member	Response	Chair's comment
Brazil	Yes, Brazil agrees.	Thanks, noted.
European Union	Agreed.	Thanks, noted
Kingdom of Saudi Arabia	<p>Saudi Arabia agrees in principle with the status outlined for the substances under consideration and provides the following clarification:</p> <ul style="list-style-type: none"> <li>• Albendazole and Ivermectin:</li> </ul> <p>At this time, these substances do not meet the criteria required for extrapolation to camelids, and therefore extrapolation cannot be supported at this stage.</p> <ul style="list-style-type: none"> <li>• Oxytetracycline (and, by association, tetracycline and chlortetracycline): <ul style="list-style-type: none"> <li>○ Saudi Arabia supports, in principle, the continuation of work on the extrapolation of MRLs for these substances in camelids, in line with the current CCRVDF criteria.</li> <li>○ However, further technical evaluation and additional information are needed to ensure that an appropriate balance is achieved between consumer protection and practical implementation before reaching a final decision.</li> <li>○ Saudi Arabia will continue to follow the ongoing technical discussions within the eWG and will provide further comments as new information becomes available.</li> </ul> </li> <li>• Future refinement of criteria:</li> </ul> <p>Saudi Arabia supports the view that some of the existing criteria may need refinement to allow for broader yet scientifically sound extrapolation to camelids, provided that consumer safety remains the primary consideration.</p>	Thanks, noted.

<p><b>Question 2:</b> It has been proposed, that when there are no common MRLs between species already established, such as in the case of ivermectin, that the EWG could recommend to CCRVDF that the MRLs from the species with the most conservative established MRLs (i.e., the lowest) be extrapolated to camelids.</p> <p>a. Can you agree that this change to criterion 3 would be appropriate for both consumer safety and for trade purposes?</p> <p>b. If you agree, are there any caveats that should be included (e.g., if the most conservative MRLs are in avian species, would this be relevant to camelids?).</p>		
Member	Response	Chair's comment
Brazil	No, Brazil does not agree with the purpose to change the criteria, in line with the Chair's comment about the wide variety of established MRLs indicates that there may be a high variability between species in pharmacokinetic parameters.	Thanks, noted.
European Union	<p>In our round 1 comments, the EU raised the possibility of considering the most conservative set of MRLs for extrapolation. However, we recognise that extrapolation in situations where MRLs are not identical across species (as in the case of ivermectin) would introduce an additional element of uncertainty. This is particularly the case if, as in the case of ivermectin, the M:T also varies across species. In this scenario, even extrapolation of the most conservative MRLs, could lead to an unacceptable consumer exposure. Consequently, upon reflection, we do not support the proposal to extrapolate the most conservative MRLs.</p> <p>a. We do not support the proposed change to criterion 3</p> <p>b. not applicable</p>	Thanks, noted.
Kingdom of Saudi Arabia	<p>Saudi Arabia could support, in principle, a modification of Criterion 3 to allow extrapolation to camelids using the most conservative (lowest) MRLs established in mammalian species. This approach would prioritize consumer safety while also offering a pragmatic solution for trade in cases where no common MRLs exist across species.</p> <p>However, the following caveats should be considered:</p> <p>Species limitation: The conservative MRLs should be derived only from mammalian donor species. If the lowest MRLs are from avian species, these should not be extrapolated to camelids due to substantial physiological and pharmacokinetic differences.</p> <p>Pharmacokinetic considerations: There should be reasonable assurance that residue-relevant pharmacokinetic behaviour (absorption, distribution, metabolism, excretion) is not fundamentally different between the donor species and camelids.</p> <p>Withdrawal periods (WPs): Applying conservative MRLs may result in longer WPs; this should be acknowledged as a precautionary measure to ensure consumer protection, without requiring new camelid-specific residue data.</p>	<p>Thanks, noted. The consensus is that the criteria, specifically criterion 3, should not be recommended for amendment by the EWG.</p> <p>It should be noted that the key pharmacokinetic data are not available to JECFA or CCRVDF to enable the comparison between camelids and other mammals.</p>

<b>Question 3:</b> Do you have any other comments or proposals on any of the points discussed above?		
<b>Member</b>	<b>Response</b>	<b>Chair's comment</b>
<b>Brazil</b>	No further comments.	Thanks, noted.
<b>European Union</b>	No.	Thanks, noted.
<b>Kingdom of Saudi Arabia</b>	<p>Yes, Saudi Arabia has the following additional comments and proposals:</p> <ul style="list-style-type: none"> <li>• <b>Withdrawal periods (WPs):</b> While WP determination lies outside the current extrapolation criteria, Saudi Arabia suggests that the eWG explicitly acknowledge that withdrawal periods established for donor species may not be directly applicable to camelids, due to potential differences in pharmacokinetic behaviour and milk composition.</li> <li>• <b>Procedural point:</b> Regarding the inclusion of tetracycline and chlortetracycline, Saudi Arabia supports the Chair's rationale based on the common Codex entry (CXM 2). If a formal procedural step is required, Saudi Arabia proposes that these compounds be added to Part V of the Priority List at the earliest opportunity to ensure consistency and regulatory clarity.</li> </ul>	<p>Thanks, noted.</p> <p>It is agreed that withdrawal periods in one species are not directly applicable to another without suitable data indicating similar residue kinetics. As noted, WP determination is the role of the national/regional authorities.</p> <p>It is agreed that suitable procedural steps should be taken to add the two additional tetracyclines.</p>

**APPENDIX III**  
**LIST OF PARTICIPANTS**

**Chair**

United Kingdom  
Sam Fletcher  
Veterinary Medicines Directorate

**Co-Chair**

Costa Rica  
Heilyn Fernández Carvajal

<b>MEMBER COUNTRIES</b>
<p><b>African Union</b> John Oppong-Otoo Food Safety Officer Economics, Trade and Marketing Unit Inter African Bureau for Animal Resources</p>
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<p><b>Australia</b> Jeevan Khurana Member Country Department of Agriculture, Fisheries and Forestry</p>
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<p><b>Brazil</b> Luana de Castro Oliveira Member Country ANVISA/Brazil</p>
<p><b>Brazil</b> Mayara Souza Pinto Member Country Ministry of Agriculture and Livestock</p>

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<p><b>China</b> Mrs. Yujie ZHANG Member Country China Institute of Veterinary Drug Control</p>
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<p><b>Denmark</b>  Katja Kragelund  Member Country  Danish Veterinary and Food Administration</p>
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<p><b>France</b>  Anne-Marie Jacques  Member Country  Anses-ANMV</p>
<p><b>Germany</b>  Dr Anke Finnah  Member Country  Federal Office of Consumer Protection and Food Safety (BVL)</p>
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