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CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 7.2 **CX/RVDF 26/28/8**

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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

OTHER MATTERS RELATED TO THE EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS OF VETERINARY DRUGS IN FOODS TO ONE OR MORE SPECIES: DISCUSSION PAPER ON EXTRAPOLATION OF MRLs FOR VETERINARY DRUGS TO EDIBLE OFFAL TISSUES OTHER THAN LIVER AND KIDNEY

(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 recommendations regarding extrapolation of MRLs for veterinary drugs to edible offal tissues other than liver and kidney, as presented in Appendix I, should do so as instructed in CL 2026/12-RVDF available on the Codex webpage/Circular Letters[1] or CCRVDF/Related Circular Letters[2]

INTRODUCTION

1. The 27th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF27, 2024) established the extrapolation electronic Working Group (EWG) 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 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 of the first workstream.

TERMS OF REFERENCE

6. The EWG should[3]:
    - Continue work on extrapolation to edible offal tissues other than liver and kidney, and in line with the discussions at CCRVDF27,
        - ensure any approach for extrapolation to edible offal tissues other than liver and kidney should incorporate a residue intake calculation conducted by the EWG to demonstrate safety for the consumer;
        - consider exploring data sources used by JMPR and JECFA to consider an estimated consumption value of 'other edible offals'; and
        - utilize available distribution data in animals to confirm that the most appropriate tissue to extrapolate is the standard tissue with the highest MRL and assess the likelihood of compliance with the proposed extrapolated value.

1 http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/
2 http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCRVDF
3 REP24/RVDF, paras 90(i)(a-c) and 90(ii)

Note: To assist the EWG in its endeavours, CCRVDF26 recommended that Codex Members submit available consumption data for edible offal to the Food and Agriculture Organization/World Health Organization Individual Food Consumption Data Tool (FAO GIFT) and the FAO/WHO Chronic Individual Food Consumption Data Summary Statistics (FAO/WHO CIFOCOss) databases.

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 18th March 2025 in English and Spanish.

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.

10. The detailed documents and comments circulated within the EWG are available in Appendix II for information.

SUMMARY OF KEY POINTS OF DISCUSSION

11. The general proposal from the EWG is to establish transparent criteria for extrapolation, to provide guidance on how to calculate dietary exposure to confirm that the extrapolated maximum residue limits (MRLs) would be safe for consumers, and then to create guidance for stakeholders on how to use the extrapolated numbers (to focus on where there might be exceedances found during inspection of goods). There is no proposal to change to CODEX procedures until both the extrapolation criteria and the related guidance are agreed.

12. The proposed extrapolation criteria have been refined so that CCRVDF would take the highest established MRL in the species for which extrapolation has been requested, put that into an adapted theoretical maximum daily intake (TMDI) model and compare the results with the acceptable daily intake (ADI). If TMDI > ADI, then an adapted estimated daily intake (EDI model will be used. If the EDI > ADI, then the next highest MRL will be tried in the models, and so on. The first calculation where either TMDI or EDI < ADI is the point of departure from where the extrapolation would be made. This would provide reassurance that consumers would be protected at the extrapolated levels.

13. The proposed calculations are in Appendix I.

14. Although desirable, it is not certain that this approach could guarantee that there wouldn't be exceedances of the extrapolated MRL in 'other edible offals' when veterinary drug products are used in accordance with good veterinary practice (GVP). This is where the EWG needs to further consider what data may be useful to inform the final recommendation.

15. There has been some debate as to what the extrapolated numbers should be called, with the majority of respondents in favour (or not opposed to) calling them 'other offal action levels' (ooALs) or simply 'Action Levels'. The use of the term 'MRL' has implications that may confuse the way these numbers should be used, such as during product approval, which is not the intention.

16. The extrapolated numbers are to enable trade between Members and to ensure consumer safety. They are not to be used in veterinary drug product authorisation and are not intended for use in domestic residues control plans.

RECOMMENDED GENERAL CONDITIONS

17. The general conditions for the establishment of extrapolated MRLs for edible offal tissues other than kidney and liver as presented in Recommendation 1, Appendix I.

COMPARISON WITH TERMS OF REFERENCE

18. With respect to the ToR, the EWG has:

    i. Ensured that the proposed approach for extrapolation to edible offal tissues other than liver and kidney incorporates a residue intake calculation to demonstrate safety for the consumer.

This has been fulfilled by proposing an intake calculation based on the use of an adapted dietary Foodbasket exposure model, to include a portion of 'other edible offals', and the use of the TMDI and/or the EDI models.

ii. Considered exploring data sources used by the Joint FAO/WHO Expert Meeting on Pesticide Residues (JMPR) and the Joint FAO/WHO Joint Expert Committee on Food Additives (JECFA) to consider an estimated consumption value of 'other edible offals'.

This has been fulfilled by interrogation of the CIFOCOss database, use of JECFA's advice on how to select the highest reliable percentile, and the Global Environment Monitoring System (GEMS) Food Cluster Diets database, to establish a proposed daily intake of 100 g for 'other edible offals'. This figure will be used in the TMDI and EDI models.

19. However, it has not yet been possible to agree an approach to: 'utilize available distribution data in animals to confirm that the most appropriate tissue to extrapolate is the standard tissue with the highest MRL and assess the likelihood of compliance with the proposed extrapolated value'.

20. Therefore, more discussion on this aspect is required. The are a number of questions that should be addressed as presented in Recommendation 2, Appendix I:

PROPOSED NEXT STEPS

21. There are some steps that need to be taken following agreement on the criteria for the extrapolation of MRLs to offal tissues other than liver and kidney as presented in Recommendation 1 and based on the replies to the issues raised under Recommendation 2, as presented in Recommendation 3, Appendix I.

OTHER CONSIDERATIONS

22. It has been clarified[4] by the JECFA Secretariat that both 'unnecessary' and 'not specified' mean the same thing regarding CCRVDF MRL listings. They mean that the substances with those listings are considered to not be a safety concern for consumers at the levels consumed after treatment with products in accordance with GVP, with a large margin of safety, and so no numerical MRLs are required. It doesn't mean, for example, that MRLs couldn't be established due to lack of data, or over safety concerns.

23. In a peer reviewed publication by several JECFA and JMPR experts, information was provided on selecting the highest reliable percentile estimate for food consumption. Using this information, a member screened the other offal consumption data in the CIFOCOss database. 'Other offal' consumption values derived from an insufficient number of subjects were excluded (i.e., fewer than 30 subjects).

24. Consumption values that did not include a mean and standard deviation were excluded, because without a mean and standard deviation, the data are unlikely to be sufficiently robust to obtain a reliable estimate.

25. This left two 'other offal' consumption values that met the criteria provided by the JECFA and JMPR experts:

Pig other offal: 49 consumers, 90th percentile = 93 g/day

Chicken other offal: 52 consumers, 90th percentile = 75 g/day

26. Because these are estimates for a mammalian species and avian species, they can be used to estimate an intake value for all other offal from the species typically considered by CCRVDF.

27. In addition, the GEMS Food Cluster Diets database provides consumption data for all types of mammalian offal on an average per capita basis. The average per capita consumption of mammalian offal ranges between 2.0 and 15.2 g/day.

28. This is how the proposed 100 g consumption value for 'other edible offals' was calculated.

29. It is noted that CCRVDF26 (2023) recommended that Codex members submit available consumption data for edible offal to the FAO GIFT and WHO CIFOCOss databases, and the EWG reiterates this recommendation.

30. According to the results of a residue monitoring study conducted by the Republic of Korea in 2024 on 'other edible offals' distributed in the domestic market, the levels of veterinary drug residues in these tissues were found to be very low in actual samples.

CONCLUSION

31. The EWG fulfilled its mandate as outlined in its ToRs, except for some issues that require further guidance from CCRVDF, and therefore were included for comments by Codex members and observers in the relevant recommendations to assist CCRVDF in its deliberations and decision-making. The results of the EWG's 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 recommendations included in Appendix I.

4 REP24/RVDF27, paras 86-87

RECOMMENDATIONS

32. Codex members and observers are invited to consider:

i. The recommendations for the extrapolation of MRLs to edible offal tissues other than liver and kidney as presented in Appendix I, based on the considerations provided in paragraphs 11-30 of this document, for comments and consideration by CCRVDF28.

APPENDIX I

CRITERIA FOR THE EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS TO EDIBLE OFFAL TISSUES OTHER THAN KIDNEY AND LIVER

(For comments)

RECOMMENDATION 1: Criteria to establish MRLs to edible offal tissues other than kidney and liver

1.1 To establish the following general conditions for extrapolation of MRLs to 'other edible offals'.

a) Extrapolations will be conducted only when compounds are added to the priority list upon request from a Member.

b) Due to the lack of data available to the CCRVDF, a call for relevant distribution and residues depletion data would be made once the substance is included on the priority list.

c) The extrapolated MRL will cover all 'other edible offals'. No refinement will be made for specific 'other edible offals'.

d) For dual use substances, CCRVDF will liaise with the CCPR to agree on the extrapolation.

e) Extrapolations to 'other edible offals' can only occur within the same species.

f) Extrapolation to 'other edible offals' cannot be based on MRLs that have themselves been established by extrapolation.

g) These criteria are for extrapolation to 'other edible offals' only. They cannot be used to extrapolate to any other edible tissues or commodities.

h) The extrapolated MRLs are not to be used for product registration, or in domestic residues control programmes. They are only for use in import/export scenarios.

i) The extrapolated MRLs are to be called 'Other Offal Action Levels (ooALs) to make it clearer that h) applies and to distinguish between these and MRLs for other commodities of animal origin, which can be used in those situations.

1.2 To use the following process to determine the MRL to be extrapolated to 'other edible offals':

Proposed calculation criteria:

- The M:T used will be the lowest of those established in the four 'usual' tissues in the same species, unless robust, relevant data from 'other edible offals' are available (Yo).
- An amended food basket will be used to make an exposure calculation. This will consist of 300 g muscle, 100 g 'other edible offals', and 50 g fat. It will also include the contributions made by milk (1500 g), eggs (100 g), and/or honey (50 g), if MRLs for these commodities have been established.
- To work out the total dietary exposure, the following calculation will be made for each edible tissue/commodity:

  MRL (µg/kg)/M:T (no units) x food basket consumption level (kg/day) = exposure (µg/person/day) (= TMDI-commodity specific)
- The highest MRL previously established in the requested species will be put through the calculation first (proposed MRL to extrapolate, Xo).
- The calculation will be conducted for each edible tissue, and the answers are summed to get the TMDI, or the EDI. (see table below).

Table of proposed calculations:

Edible commodity	Daily consumption (kg)	MRL (µg/kg)	M:T	Amount per edible commodity (kg)
Muscle	0.3	Established MRL (TMDI), or use median residue (EDI) (Xm)	Ym	0.3*Xm/Ym
Fat	0.05	Established MRL (TMDI), or use median residue (EDI) (Xf)	Yfm	0.05*Xf/Yf
Milk	1.5	Established MRL (Xmi)	Ymi	1.5*Xmi/Ymi
Eggs	0.1	Established MRL (Xe)	Ye	0.1*Xe/Ye
Honey	0.05	Established MRL (Xh)	Yh	0.05*Xh/Yh
Other edible offals	0.1	Proposed MRL to extrapolate (Xo)	Lowest of all established M:Ts in liver, kidney, fat and muscle. (Yo)	0.1*Xo/Yo
(adjusted) TMDI = Estimated total daily intake (µg/person):				= Sum of the above.

- A comparison will then be made as to whether the estimated total daily intake (adjusted TMDI) exceeds the established ADI.
- If TMDI > ADI for the highest established MRL for a species, then the median residue approach (EDI) should be used as a refinement.
- The median residue approach takes the median residue from the residue depletion data used by JECFA to establish the MRLs for muscle and fat, at the timepoint used to set the MRL, and uses that in place of the muscle/fat MRLs (Xm, Xf,) in the calculation above.
- If EDI> ADI, then the next highest established MRL would be used (as Xo) in the 'other edible offals' row in the table above.
- The first value of Xo used, as per the sequence described above, that leads to the conclusion that TMDI or EDI < ADI, will be considered for recommendation for extrapolation to 'other edible offals' to CCRVDF.
- Consumer safety (i.e., the likelihood that the extrapolated MRLs would be adhered to when products are used in accordance with GVP) is then confirmed by use of additional data (to be decided).

1.3 To recommend that the EWG undertakes future work as follows:

a) To determine what data types would be useful to reassure CCRVDF that the extrapolated MRLs would likely be adhered to when veterinary drug products are used in accordance with Good Veterinary Practice (GVP).

b) To conduct a pilot on 2-3 substances, as decided by CCRVDF, to establish whether the recommended processes would be suitable, and to test different data types, as available, that may assure CCRVDF that extrapolated MRLs would likely be adhered to when veterinary drug products are used in accordance with Good Veterinary Practice (GVP).

c) To establish guidance for stakeholders on the utilisation of the extrapolated MRLs (or ooALs), to focus on cases where they may be exceeded.

Definitions

- ADI = Acceptable Daily Intake.
- CCPR = Codex Committee on Pesticide Residues
- CCRVDF = Codex Committee on Residues of Veterinary Drugs in Foods
- EDI = Estimated Daily Intake.
- GVP = Good Veterinary Practice.
- MRL(s) = Maximum Residue Limit(s)
- ooAL = other (edible) offal Action Level = A concentration of residue (expressed in mg/kg or µg/kg on a fresh weight basis) resulting from authorized use of a veterinary drug that is recommended by the Codex Alimentarius Commission to be recognized as acceptable in or on edible offal tissues other than liver and kidney, above which action could be taken.
- 'Other edible offals' = edible offal tissues other than liver and kidney.
- MRL = Maximum Residue Limit.
- M:T = Ratio of marker residue to total residue
- TMDI = Theoretical Maximum Daily Intake.

RECOMMENDATION 2: It has not yet been possible to agree to an approach to: 'utilize available distribution data in animals to confirm that the most appropriate tissue to extrapolate is the standard tissue with the highest MRL and assess the likelihood of compliance with the proposed extrapolated value'. To reach an agreement, the following questions should be addressed:

1. What data type would be considered relevant to provide assurance that extrapolated MRLs/ooALs would be unlikely to be exceeded under GVP?

   Proposed data types for discussion:

   i. TRR and/or cold distribution data in the target species/related species/unrelated species

   ii. Water/lipid partitioning data – $LogP_{ow}$,

   iii. Data from related compounds to be used in a read-across approach.

2. Where it is known that a particular tissue (among the 'other edible offals') is driving the potential exceedance of the extrapolated MRL, how might that be dealt with? For example, ractopamine distributes preferentially to the lungs and some products will be orally administered and not be systemically available, such as those whose target of action is within the gut contents (e.g. wormers, antibiotics) and so might have higher residues in the stomach/intestine.

3. Is there any situation in which CCRVDF would want to further refine which specific 'other edible offals' the extrapolated figures referred to?

RECOMMENDATION 3: Proposed next steps for the extrapolation of MRLs to edible offal tissues other than liver and kidney.

3.1 To conduct a pilot calculation on 2-3 veterinary drug substances to test which data types (available in the public domain) would be considered sufficient to reassure CCRVDF that the extrapolated MRLs/ooALs are likely to be adhered to when veterinary drug products are used in accordance with GVP.

3.2 To agree on what data types would be sufficient to reassure CCRVDF that the extrapolated MRLs/ooALs are likely to be adhered to when veterinary drug products are used in accordance with GVP.

3.3 To create guidance on how to use the extrapolated figures for those in the field.

APPENDIX II

Appendix to the report from the electronic working group on extrapolation of maximum residue limits for veterinary drugs to one or more

EWG EXCHANGES

(For information)

Kick-off message

This EWG has been established to create a methodology for extrapolating MRLs to 'other edible offals' within a species, for proposal to CCRVDF28. It will also consider any requests for extrapolation by Members.

Extrapolation to 'other edible offals'

Extrapolations will be conducted upon request from a Member, on a case-by-case basis.

When considering the extrapolation of MRLs to 'other edible offals', CCRVDF will be looking to have only one MRL for a species that covers all edible offals other than kidney and liver.

CCRVDF agreed that there will be a tiered approach wherein the highest MRL already established for a substance in any edible tissue (excluding milk and eggs) will be considered first.

CCRVDF agreed that there will be a consideration of consumer safety.

- It has been suggested that the TMDI approach be used, as it is simple to use, conservative, and it has been noted (by the JECFA Secretariat) that the available food consumption data are unreliable for 'other edible offals', and so the usual databases of food consumption used by JECFA would not be useful in this case.
- If the calculated TMDI exceeds the established ADI when using the highest established MRL for a substance in the calculations, then the next highest established MRL will be considered for extrapolation.
- The process would then proceed as above, until an MRL could be recommended that would not lead to the calculated TMDI greater than the established ADI.

CCRVDF27 agreed that any substance where the established MRLs were either 'unnecessary' or 'not specified' could be extrapolated directly to 'other edible offals'.

Discussion:

It was noted that there would be very few data available on the distribution of veterinary drug substances into 'other edible offals', and the M:T in each offal would also not be available.

Thus, the EWG could focus on establishing a method that uses only the data used to establish the current MRLs.

To achieve this, we would need to determine a suitable estimate of

- M:T, and
- dietary exposure

Marker to Total Residue ratio (M:T):

In order to estimate M:T in 'other edible offals', USA had proposed a method based on the following steps:

- Calculate the magnitude of difference between the highest and lowest M:T in edible tissues with already established MRLs for the substance under evaluation, in the species for which extrapolation is requested. This can be used as an 'uncertainty factor' (UF). Thus, the calculation would be:

(highest M:T/(lowest M:T) = UF

- Calculate the average (mean) M:T for that substance for all established MRLs.
- Divide the mean M:T by the UF to get the value of the M:T for 'other edible offals' to be used in the exposure calculation, thus:

(mean M:T)/UF = $M:T_{\text{other edible offals}}$

Dietary Exposure:

It was also suggested that those that consumed 'other edible offals' would not consume them *in addition* to the current Food Basket, but *instead of* some or all of the tissues that currently make up the food basket (i.e., muscle, liver, kidney, and fat (skin/fat)).

Thus, the following table was created (by USA) to show which dietary scenarios could be considered:

Table 1. Possible Dietary Scenarios Used to Estimate Dietary Consumption of Other Offal

Tissue	Diet 1	Diet 2	Diet 3	Diet 4	Diet 5	Diet 6	Diet 7	Diet 8	Diet 9	Diet 10	Diet 11	Diet 12	Diet 13	Diet 14	Diet 15
Muscle (kg)	0.3	0.3	0.3	0	0.3	0.3	0.3	0	0	0	0.3	0	0	0	0
Liver (kg)	0.1	0.1	0	0.1	0.1	0	0	0.1	0.1	0	0	0.1	0	0	0
Kidney (kg)	0.05	0	0.05	0.05	0	0.05	0	0.05	0	0.05	0	0	0.05	0	0
Fat/skin (kg)	0	0.05	0.05	0.05	0	0	0.05	0	0.05	0.05	0	0	0	0.05	0
Other offal (kg)	0.05	0.05	0.1	0.3	0.1	0.15	0.15	0.35	0.35	0.4	0.2	0.4	0.45	0.45	0.5
Total (kg)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5

The TMDI model assumes that a typical person consumes 0.5 kg of meat, 0.1 kg of eggs,1.5 kg of milk, and 0.05 kg of honey daily for a lifetime, with the 0.5 kg of meat being comprised of 0.3 kg muscle,0.1 kg liver, 0.05 kg kidney, and 0.05 kg fat (skin with fat).

To work out the total residue consumed, the following calculation is made for each edible tissue (including milk, eggs, and honey):

MRL (µg/kg) / M:T (no units) x food basket consumption level (kg/day) = exposure (µg/person/day)

This calculation is conducted for each edible tissue and the answers are summed to get the TMDI.

If TMDI < ADI in all dietary scenarios, then the extrapolated MRL could be considered to be 'safe' for consumers. If not, then the next highest MRL would be used in the calculations, and so on.

An example was presented to demonstrate how this approach would work.

Fall-back approach:

If the methodology described above leads to the conclusion that direct extrapolation of an established MRL to 'other edible offals' could be a consumer safety risk, then the EWG could consider what MRL may be calculated, based on the portion of the ADI not used for the other tissues (taking into account dual use compounds, potential future uses of the substance in dairy/eggs/honey, and analytical limitations).

Although this would not be 'extrapolation' *per se*, it could still provide a numerical recommendation for CCRVDF to consider and would be 'safe' for consumers.

Other Information:

It was noted that JMPR/CCPR had experience of estimating consumption in such cases, and that their methodology might be useful in this case.

- Mammalian – the JMPR will recommend that the MRL for 'other edible offal' is set based on the highest residue from kidney and liver.
- Poultry– the JMPR will recommend that the MRL for 'other edible offal' is set based on the highest residue from kidney and liver, although this is usually based on the residue in liver, as kidney samples are not typically taken in poultry feeding studies.

It was noted that both CCPR and CCRVDF use the same definition for 'edible offal'.

For dual use compounds, harmonisation with MRLs established by CCPR (if available) is desirable.

Questions for the EWG:

1. Do you agree that the TMDI model can be used to evaluate consumer safety in this scenario?
2. Do you agree with the proposed methodology for calculating M:T?
    a. Another option could be to use the lowest established M:T.
3. Do you agree with the proposal for calculating dietary exposure using the various dietary exposure scenarios?
4. Do you agree with using the 'fall-back' approach where the main approach does not work?
5. Do you have any additional comments or concerns?

Round 1:

Table of comments and Chair's considerations:

	Question 1: **Do you agree that the TMDI model can be used to evaluate consumer safety in this scenario?**	
Member	**Responses**	**Chair's comments**
Brazil	Brazil does not agree.	Noted. This position is expanded upon under question 5.
Costa Rica	Yes, the approach using the TMDI seems appropriate, considering that there is not much pharmacokinetic/residue data for these tissues.	Noted.
European Union	Yes.	Noted.
Republic of Korea	Agree.	Noted.
New Zealand	The paper states that "the highest MRL already established for a substance in any edible tissue (excluding milk and eggs) will be considered first." This appears to conflict with the next point, wherein the tissue with the highest MRL is considered after the TMDI analysis. Perhaps this is a matter of phrasing? It would be logical that both apply in a stepwise fashion: the starting point would be a TMDI calculation that includes 'other edible offals' with an MRL set to align with the highest edible tissue MRL, and if that exceeds the established ADI then the next is assigned the highest edible tissue MRL and so on until TMDI<ADI. Regarding the statement "any substance where the established MRLs were either 'unnecessary' or 'not specified' could be extrapolated directly to 'other edible offals'": suggest this is qualified to state this will apply where there is sufficient data to evaluate but the 'unnecessary' determination was made. There are situations where MRLs were not specified because there was insufficient or no data available to quantify residues to determine an MRL.	The Chair apologises for not being clearer in the description of the proposed process. I think we are on the same page though regarding the stepwise approach. It has been clarified by the CODEX Secretariat that both 'unnecessary' and 'not specified' mean the same thing regarding CCRVDF MRL listings. It means that the substances with those listings are considered to not be a safety concern for consumers at the levels consumed after treatment with products in accordance with GVP, with a large margin of safety, and so no numerical MRLs are required. It doesn't mean, for example, that MRLs couldn't be established due to lack of data or over safety concerns.

Saudi Arabia	Yes, Saudi Arabia agree that the Theoretical Maximum Daily Intake (TMDI) model can be used to evaluate consumer safety, particularly in situations where more refined exposure or toxicological data are lacking. The TMDI approach serves as a useful preliminary tool, relying on conservative assumptions and maximum permitted levels to estimate potential exposure. However, it should ideally be followed by more refined assessments when additional data become available.	Noted. This chair would always encourage data submission to JECFA for full evaluation of MRLs as a preferred approach, with as much data in as many animal species as possible. However, in the situation where CCRVDF is asked to extrapolate MRLs to 'other edible offals', we are working with minimal data in the tissues being extrapolated to. If those data were available for each substance in each species, then it could form part of the criteria for extrapolation, but we are not in a position where those data are readily available. We could say that, for example, where the M:T is known for a range of 'other edible offals' in the species of concern, at the GVP withdrawal period, we could use the lowest of those in the calculation, rather than the lowest M:T of the 'usual' edible tissues. It may be possible to incorporate this approach at the refinement stage of the process, depending on availability of the data. However, it would be better, in the opinion of the chair, to make this process as simple as possible.
United States	The United States thinks that a TMDI type model, with appropriate modifications, can be used to evaluate consumer safety.	Noted. This position is expanded upon under each question.

	Question 2: **2. Do you agree with the proposed methodology for calculating M:T?** **a. Another option could be to use the lowest established M:T.**	
Member	**Responses**	**Chair's comments**
Brazil	Brazil does not agree.	Noted. This position is expanded upon under question 5.
Costa Rica	Yes, since the approach seems sufficiently conservative (it uses an average of the M:T). Although the other proposal of using the lowest M:T is even more conservative, this could lead to difficult-to-meet MRLs, so the original proposal of using the average of the M:T seems more appropriate.	Noted; however, the USA has further comments on this proposal (see below) which indicate that using the lowest M:T might be more appropriate.
European Union	The proposed method offers a potential way to use the available data to make worst-case consumer exposure estimates. However, we are concerned that the MRLs extrapolated from this approach may lead to unforeseen difficulties – please see comments below.	Noted. This position is expanded upon under subsequent questions.
New Zealand	While this is logical as a general principle for systemic distribution, there may need to be case-by-case considerations for compounds that may present a more localised potential for increased residues due to administration route. For example, oral administration of an anthelmintic compound that remains resident in the rumen in the form of a slow-release bolus may present a different residue profile with respect to edible offals from the upper digestive tract than a similar formulation administered topically or parenterally.	This concern is noted. It is agreed that locally acting drugs may have higher residues and potentially different metabolic profile than residues in the 'usual' four tissues, which are exposed via systemic circulation, especially those drugs that target intestinal microbes or parasites and are administered orally. Systemic bioavailability is often relatively low for these substances, as they are designed to work in the GI tract. This may be addressed using the 'Action Level' approach proposed by the United States, or by excluding specific substance types from the proposed extrapolation.
Republic of Korea	Agree.	Noted.
Saudi Arabia	Yes, Saudi Arabia agree with the proposed methodology for calculating the M:T (Ratio of Marker Residues to Total Residues), provided that the approach is transparent, scientifically justified, and based on reliable input data. The calculation must account for realistic consumption levels, appropriate safety factors, and should align with internationally recognized risk assessment standards, with the proposed methodology for calculating M:T.	Noted and agreed. It has been noted by a Member (see below) that the proposed approach may skew the calculated M:T and make it too extreme, or unrealistic. As such, it has been proposed that the lowest M:T in the other four tissues should be used instead.

United States of America	Since proposing the referenced methodology for estimating an M:T for other offal, the United States has performed additional analyses of the available M:T ratios in the traditional tissues. These indicate that the referenced approach can result in the offal M:T ratio being artificially skewed. The United States agrees with the alternative suggested by the Chair and co Chair to use the lowest M:T of the four traditional tissues as the estimated M:T for other offal tissues. This is justified by the four traditional tissues including liver and kidney, which generally have the greatest metabolic capacity of all tissues. Although liver and kidney generally are the tissues with the greatest metabolic capacity, the M:T ratio is lowest in fat for some veterinary drugs evaluated by JECFA thus far. In these cases, the veterinary drug is a fat-soluble compound (LogP > 0). This is reasonable to expect in some cases as circulating metabolites of fat-soluble compounds would have an innate affinity for fat, thereby lowering the M:T ratio beyond that of liver and kidney. To this end, CCRVDF could consider that the M:T data in the four standard tissues is representative of the range of M:T values that would be found in other edible tissues. In other words, the likelihood that the M:T in other offal tissues is lower than the M:T values in the four standard tissues is low. Therefore, from a risk-based perspective, CCRVDF could extrapolate the lowest M:T value from the four standard meat tissues to other offal tissues.	Noted and agreed. The lowest M:T of the four 'usual' tissues would be appropriate for this use.

	Question 3: **Do you agree with the proposal for calculating dietary exposure using the various dietary exposure scenarios?**	
Member	**Responses**	**Chair's comments**
Brazil	Brazil does not agree.	Noted. This position is expanded upon under question 5.
Costa Rica	Yes, using diverse food baskets provides a glimpse into possible consumption scenarios, further protecting consumers' health.	Noted.
European Union	While the proposed method offers a potential way to use the available data to assess various exposure scenarios, we are concerned that MRLs extrapolated from this approach may lead to unforeseen difficulties – please see comments below.	Noted and agreed. It has become clear that if MRLs are set too low, then residues may be found in 'other edible offals' that exceed this level, even after treatment in accordance with GVP. This would be an unacceptable outcome.
Republic of Korea	Agree.	Noted.
New Zealand	There is some concern with the theory that 'other edible offals' can always be considered a replacement of some or all tissues currently in the food basket. At least in some instances, 'other edible offals' are consumed in conjunction with other foods rather than instead of (e.g., casings used in sausages), though it is not expected that 'other edible offals' will contribute significantly to the overall food basket. Perhaps the emphasis should be on the consumption of these products being so generally minimal that they will not significantly increase dietary exposure and therefore total consumption is more or less unchanged. This could be expressed by setting 'other edible offals' consumption at a subset estimated low value such as 0.025 in the consumption model as described in Table 1, or at half the average kidney consumption, for dietary exposure calculation purposes.	This concern is noted; however, CCRVDF should take into account consumers of all types, including those that consume relatively large amounts of 'other edible offals'. Another Member has also considered this issue and proposed that the contribution made by 'other edible offals' should be included in the food basket instead of both liver and kidney, rather than as an addition (see below). There may also be concerns with this approach, so the EWG will be consulted.
Saudi Arabia	Yes, Saudi Arabia support the use of various dietary exposure scenarios (e.g., worst-case, typical, and subpopulation-specific scenarios) in calculating dietary exposure. Scenario analysis allows for a more flexible and realistic estimation of exposure, especially when detailed consumption data are limited. It also enables a better understanding of potential risks to different segments of the population.	Noted.

United States of America	The referenced table provides one way in which dietary exposure could be calculated. However, it likely will yield consumption scenarios that are unlikely to occur, which will result in extrapolations that are more restrictive than necessary to protect consumer health. Since providing the table depicting the various dietary substitutions, the United States has further investigated the available data for other offal consumption. In a peer reviewed publication by several JECFA and JMPR experts, information was provided on selecting the highest reliable percentile estimate for food consumption. Using this information, the United States screened the other offal consumption data in the CIFOCOss database. Other offal consumption values derived from an insufficient number of subjects were excluded (i.e., less than 30 subjects). In addition, consumption values that did not include a mean and standard deviation were excluded, because without a mean and standard deviation, the data are unlikely to be sufficiently robust to obtain a reliable estimate. This left two other offal consumption values that met the criteria provided by the JECFA and JMPR experts: • Pig other offal: 49 consumers, 90th percentile = 93 g/day • Chicken other offal: 52 consumers, 90th percentile = 75 g/day Because these are estimates for a mammalian species and avian species, they can be used to estimate an intake value for all other offal from the species typically considered by CCRVDF. In addition, the GEMS Food Cluster Diets database provides consumption data for all types of mammalian offal on an average per capita basis. The average per capita consumption of mammalian offal ranges between 2.0 and 15.2 g/day. Therefore, based on the CIFOCOss and GEMS Food Cluster Diets databases, CCRVDF could consider 100 g/day to be a conservative estimate of other offal intake for an offal TMDI model. Consumers of offal tissues are unlikely to consume the traditional TMDI amount of liver (100 g) and kidney (50 g) plus a full serving of other offal tissues (100 g as described above) every day of their entire life. For an offal TMDI model, the United States suggests that liver and kidney be excluded because consumers of these offals previously have been accounted for by the existing MRLs and risk assessment. To this end, CCRVDF could consider the offal TMDI food basket to consist of 300 g muscle, 50 g fat, and 100 g other offal.	The Chair thanks the United States for their work on this, and for critiquing their own proposals. The Chair has concerns regarding the accuracy of these survey-based data but notes that these are the only data available for potential consumption levels for 'other edible offals'. It is noted that CCRVDF26 recommended that Codex Members submit available consumption data for edible offal to the FAO GIFT and WHO CIFOCOss databases, and the Chair reiterates this recommendation. It is felt that these data may be unreliable for this purpose due to the small number of consumers (particularly those that consume high levels of 'other edible offals') included in the database. However, as there are no other suitable data available, they can be used as a starting point. It may be acceptable to replace both kidney and liver in the food basket with 'other edible offals', but it would be considered appropriate by the Chair to use the whole amount (i.e., 150 g/day) to be conservative (Diet 7 in the original proposal).

	Question 4: **Do you agree with using the 'fall-back' approach where the main approach does not work?**	
Member	**Responses**	**Chair's comments**
Brazil	Brazil does not agree.	Noted. This position is expanded upon under question 5.
Costa Rica	No, as this is not really an extrapolation (which is the mandate of this EWG). This approach could be added as a suggestion for consideration by CCRVDF if it is found that for many of the edible offals the proposed extrapolation framework does not work, but only in this case, and then CCRVDF would be able to consider if this fall-back approach is advisable or not. But to propose this method when the EWG has only just started proposing a possible extrapolation method for these offals seems a bit premature.	Noted and understood.
European Union	No – see additional concerns below.	Noted. This position is expanded upon under question 5.
Republic of Korea	The Republic of Korea does not agree with the suggested fall-back approach. As exposure levels approach the Acceptable Daily Intake (ADI), the safety margin becomes narrower. For substances with estimated exposures already exceeding 90% of the ADI, applying the fall-back approach may result in the ADI being exceeded. Therefore, we have concerns about applying this approach in such cases.	Noted.
New Zealand	Yes.	Noted.
Saudi Arabia	Yes, Saudi Arabia agree with using the 'fall-back' approach when the primary methodology is not feasible, provided it is scientifically reasonable and sufficiently protective of public health. The fall-back approach should be clearly documented, including the rationale for its use and any assumptions made.	Noted and agreed, if this approach is taken forward.

United States of America	In principle, the United States agrees with the fall-back approach. The United States also suggests that, when the main approach does not work, CCRVDF consider options to refine the model before proceeding to the fall-back approach. If the offal TMDI model indicates a possible exceedance of the ADI, CCRVDF could use the existing risk assessment information from JECFA to further refine the exposure model, if possible. For example, if the first iteration of the offal TMDI model results in exceedance of the ADI, CCRVDF could use the JECFA derived median residue values for the other tissues in the model (i.e., muscle and fat) instead of the MRL for those tissues, as JECFA has determined that the median is the "best point estimate of the central tendency over a prolonged period of time." Refinement of a dietary exposure model is consistent with Codex Guidelines established by CCFA. The guidelines note that estimates of dietary exposure can start with the simplest model (i.e., TMDI) and then move to a more refined model. Therefore, CCRVDF could take such an approach when extrapolating MRLs to other offal tissues.	The Chair thanks the United States for their useful comments. As others have stated, the proposed 'fall-back' position is not 1:1 extrapolation and may lead to MRLs that are too low to enable trade. The Chair would ideally like to have the simplest approach possible. The proposal outlined here appears to be quite simple on the surface, but it is not clear that the EWG would have the median data available for all substances. The consensus from respondents is that the EWG is not keen to use the fall-back approach proposed in the first round. The approach proposed by USA would likely make this step redundant, so it would be reasonable to remove it from the stepwise approach.

	Question 5: **Do you have any additional comments or concerns?**	
Member	**Responses**	**Chair's comments**
Brazil	Yes. Brazil understands that due to the absence of specific data, the presented proposal introduces inferences that increase the uncertainties of the extrapolation calculation, making it less accurate. Therefore, given the complexity of the topic and the current lack of sufficient data, adopting the JMPR/CCPR approach represents a more appropriate and conservative strategy. This methodology is easy to apply, internationally recognized, and safe because it is based on using the highest residue between the liver and kidney, which are the organs responsible for the metabolism and excretion of the molecules.	Noted. It would be good to have a simple, harmonised, approach. However, if the CCPR approach is as simple as extrapolating the MRL from the tissue (either liver or kidney) with the highest residues, which often corresponds to the tissue with the highest MRL, to 'other edible offals', then the major concern that the EWG has identified would not be resolved.

European Union	The EU is concerned that the proposed approach may lead to unforeseen difficulties. Across the globe, veterinary drugs are routinely used in line with GVP, and existing MRLs have been established in a manner that ensures that, when used in this way, compliance with the MRLs is achieved. Given the diversity of edible offal tissues, we do not know whether use of existing products in line with GVP would lead to compliance with 'other offal' MRLs derived as proposed. There is a real risk that for some existing products (perhaps many existing products), the 'other offal' MRLs could bring established withdrawal periods into question, and exporters of 'other offal' may find that, despite the fact that veterinary drugs have been used in accordance with established GVP, the produce they are exporting does not comply with the extrapolated MRLs. In CCRVDF's previous work on extrapolation, i.e., when we considered extrapolating across species, an important assumption was that authorisation of products for the new species would require the establishment of GVP in the new species (i.e. the establishment of withdrawal periods that ensure compliance with the extrapolated MRLs). The current exercise is quite different because we are working within species for which GVP is already established. It is critical that the extrapolated MRLs do not bring established GVP into question. It is significant that, until now, Codex MRLs have been considered to be protective for consumers across the globe (even if their diets do not conform to the standard food basket). If Codex were to extrapolate MRLs as proposed and it turned out that use of veterinary drugs according to established GVP leads to exceedance of extrapolated MRLs, the validity of the position that Codex MRLs ensure consumer safety could be questioned. It is also important to note that facilitation of international trade was a primary motivation for developing an approach for extrapolation to 'other offal' tissues. It is therefore critical that CCRVDF should avoid adopting an approach that could actually create difficulties for international trade and unfairly penalise products and producers that have used veterinary drugs according to GVP. The EU accepts that CCRVDF needs to be able to provide reasoning to support the safety of extrapolated MRLs. We consider that, in the absence of relevant supporting data, this is challenging to achieve with high certainty. The extrapolation working group could further consider what data may be gathered to ensure that MRLs extrapolated to 'other offal' are consistent with existing GVP and withdrawal periods.	Noted and agreed. This concern highlights that residues of veterinary drugs in 'other edible offals' have been neglected by the current methodology used. It is entirely possible that residues of veterinary drugs in 'other edible offals' (particularly those that act locally in the GI tract, as mentioned above) could be higher or much higher than those seen in the 'usual' four tissues and have different metabolic profiles. It must be recognised that extrapolation of MRLs to 'other edible offals' may introduce new and unforeseen problems, since there are very few data available in relevant species on residue levels in 'other edible offals'. CCRVDF needs to be sure that the benefits to trade outweigh the risks that may come in terms of confidence in consumer safety for those consuming relatively high levels of 'other edible offals'. If residues of veterinary drugs are consistently found in certain 'other edible offal' commodities above the extrapolated MRLs, then this would also affect trade between Members. In terms of what data may be required to ensure that MRLs extrapolated to 'other edible offals' are consistent with existing GVP and withdrawal periods, ideally, we would have (radiolabelled) distribution data in the species concerned, at the timepoint corresponding to the shortest GVP withdrawal period. These data may more appropriately be used by JECFA to set standard MRLs. Nonetheless, these data could also be used by the EWG when considering extrapolations. The (non) availability of such data is always going to be an issue.

Republic of Korea	In the process of establishing extrapolation principles for other edible offals currently under discussion, the most important consideration is to set standards at a rational level based on scientific evidence. This approach is fundamentally consistent with the principles applied in setting Maximum Residue Limits (MRLs) for veterinary drugs under Codex and other international frameworks. According to the results of a residue monitoring study conducted by the Republic of Korea in 2024 on other edible offals distributed in the domestic market, the levels of veterinary drug residues in these tissues were found to be very low in actual samples. These findings raise concerns that applying high residue limits—such as those established for liver or kidney—to other edible offals may result in unnecessarily excessive standards, considering the actual levels detected. Therefore, in order to provide scientific justification for the currently proposed approach of sequentially applying the highest established MRL within the same species, it is essential to first collect actual residue data for at least some types of other edible offals. Such data would serve as a crucial scientific foundation for building a more proportionate and evidence-based extrapolation framework.	Noted and agreed. CCRVDF certainly needs to be able to set reasonable and defensible MRLs. It is reassuring that residues levels are low in 'other edible offals' on the domestic market when analysed, but these data are not from controlled studies. The length of the Withdrawal Periods cannot be known for these samples, and many producers wait much longer than the authorised WP before slaughter of the treated animals, depending on the drugs used and for what purposes (indications). It is also agreed that in an ideal world, we would gather available data in order to reassure ourselves that we are not exposing Members to consumer safety or trade issues.

United States of America	A summary of the United States' responses is provided. • A TMDI type model can be used to evaluate consumer safety. • The lowest M:T value from the four standard meat tissues can be extrapolated to other offal tissues. • The other offal TMDI food basket can consist of 300 g muscle, 50 g fat, and 100 g other offal. • The other offal TMDI model can be used first to determine if the highest MRL can be extrapolated to other offal. If exceedance of the ADI seems possible, refinement of the model is conducted before testing the next highest MRL. • The United States agrees, in principle, with the fall-back approach if the initial approach with model refinement does not work. In addition, the United States provides some additional comments for consideration. • Although a TMDI type model can be used to assess consumer safety, the United States thinks that the EWG and CCRVDF should discuss and consider the potential implications of establishing numerical residue limits for other offal in the absence of residue data in these tissues under GVP. • The approach should not exclude the use of residue data or distribution information to inform the decision if these data and information are available. For example, the process could include a call for data or information from CCRVDF members or a literature search. The data and information would be used to assess the likelihood of compliance with the value assigned to other offal. • CCRVDF should consider using a term other than MRL to describe the residue value that is extrapolated to other offal because the value is not derived from residue data in other offal tissues generated under GVP. CCRVDF could consider calling the extrapolated value an Other Offal Action Level (ooAL). This would acknowledge that the maximum residue concentration in these tissues under GVP is not known. Parallelling the ongoing work on carryover, the United States suggests the following definition: ○ Other Offal Action Level: A concentration of residue (expressed in mg/kg or µg/kg on a fresh weight basis) resulting from authorized use of a veterinary drug that is recommended by the Codex Alimentarius Commission to be recognized as acceptable in or on edible offal tissues other than liver and kidney, above which action should be taken. • Because the residue value that is extrapolated to other offal is not based on data generated in other offal tissues, the United States suggests that CCRVDF consider utilizing a complementary approach that relies on Other Offal Action Levels and a Codex Guideline document, like the one agreed to by CCRVDF27 to address residues in food caused by carryover.	It has become clear from the responses provided by Members, that the extrapolation to 'other edible offals' is not an easy consideration to make. A very important point made is, that because JECFA and CCRVDF do not generally have data available for residues in 'other edible offals', and definitely not in all species where MRLs exist, that CCRVDF cannot be sure that any extrapolation made to these tissues would have a positive effect on trade, due to the unknown levels of residues in 'other edible offals' after the use of vet drugs in accordance with GVP. Having residues >MRL in 'other edible offals' after use of veterinary drugs in accordance with GVP would create problems in international trade and be an unwanted outcome of the extrapolation. It has been generally agreed that use of veterinary drugs according to GVP does not raise concerns for consumer safety, and if it were the case that such extrapolated MRLs would lead to GVP having to be adjusted (such as requiring a longer withdrawal period for some vet drugs) in order to enable trade, then this would be an unacceptable outcome of the extrapolation. The United States' suggestion of an 'Action Level' approach for the extrapolated MRLs is one to consider, although there may be concerns around the practicality of such an approach. • For dual use compounds that have Codex MRLs for 'other edible offals' established by CCPR, CCRVDF should take no action because a Codex MRL already exists. ***Chair's comment: CCRVDF should add them to their official listings, whether 'ooALs' or MRLs, if extrapolation were to be requested.***

	Such an approach would recognize that the concentration of residues in other offal might exceed the extrapolated residue value but still not be a concern for consumer health. The guideline would describe how to evaluate residues in other offal that exceed the Other Offal Action Level. • For dual use compounds that have Codex MRLs for offal established by CCPR, CCRVDF should take no action because a Codex MRL already exists. • Extrapolations to other offal should be done within the same species. • Extrapolation to other offal should only be done if the reference Codex MRLs in a species are those recommended by JECFA the risk assessment. • A process for other offal extrapolation should note that CCRVDF will continue to first establish MRLs in the four standard tissues based on a JECFA risk assessment. • • Extrapolation to other offal should occur only if compounds are added to the priority list.	• Extrapolations to 'other edible offal' should be done within the same species. ***Chair: agreed.*** • Extrapolation to 'other edible offal' should only be done if the reference Codex MRLs in a species are those recommended by the JECFA risk assessment. ***Chair: agreed*** • A process for 'other edible offal' extrapolation should note that CCRVDF will continue to first establish MRLs in the four standard tissues based on a JECFA risk assessment. ***Chair: agreed.*** • Extrapolation to 'other edible offal' should occur only if compounds are added to the priority list. ***Chair: agreed.***

Discussion of Members' responses to the initial proposals.

The Chairs thank Members for their responses. It has become clear from the responses provided by Members, that the extrapolation to 'other edible offals' is not an easy consideration to make. An important point made is, that because JECFA and CCRVDF do not generally have data available for residues in 'other edible offals', and definitely not in all species where MRLs exist, that CCRVDF cannot be sure that any extrapolation made to 'other edible offals' would have a positive effect on trade, due to the unknown levels of residues in 'other edible offals' after the use of vet drugs in accordance with GVP. Having residues >MRL in 'other edible offals' after use of veterinary drugs in accordance with GVP could create problems in international trade and be an unwanted outcome of the extrapolation.

It has been generally agreed that the use of veterinary drugs according to GVP does not raise concerns for consumer safety, and if it were the case that such extrapolated MRLs would lead to GVP having to be adjusted (such as requiring a longer withdrawal period for some veterinary drugs) in order to enable trade, then this may be an unacceptable outcome of the extrapolation.

One Member noted that the CCPR already have criteria established for extrapolation of MRLs to 'other edible offals', so it would make sense to use the same methodology for CCRVDF.

It can be agreed in principle that it would be ideal to have a common approach with CCPR. However, it is not clear how the CCPR approach would solve the issue highlighted above. It should be noted that pesticides are not intended to be used in or on animals; they are contaminants in feed. The animals are exposed to pesticides at relatively low levels compared to veterinary drugs that can be administered directly to the animals at therapeutic doses. It would be useful to gather the experiences of Members on the implementation of the CCPR approach and see if any problems have arisen.

One Member made a proposal to counter this potential problem. That is, to use a new term for the extrapolated values, of 'Other Offal Action Levels', or ooALs, and has proposed the development of a CCRVDF guideline to explain the concept and how it could be used. This level would then potentially not be an obstacle to trade, but a level at which further consideration should be made, in line with the approach taken for carryover of unintended and unavoidable residues in animal feedingstuffs agreed at CCRVDF27. See Annex 2 for further information. This approach may complicate things for authorities that receive goods which include 'other edible offals' with residues above the extrapolated MRLs.

It seems at this stage, that there are four options for the EWG recommendations to CCRVDF:

1. To establish criteria and call the extrapolated levels 'MRLs',
2. To establish criteria and call the extrapolated levels 'ooALs' and recommend further work to create the necessary guidance, as per the carryover EWG.

3. Use the established CCPR approach.
4. To note that extrapolation of MRLs to 'other edible offals' for veterinary drug substances may lead to more problems than it solves, and to recommend that this work is halted until further data are available that may be used to confirm that the extrapolated MRLs would likely be conformed to under GVP.

The responses from Members to the first list of questions and the Chair's comments on those are in Annex 1 of this document.

Annex 2 contains the 'Action Level' approach and includes some of the Chair's thoughts.

The Chair has considered the responses from the EWG and proposes the following calculations for establishment of extrapolated MRLs for 'other edible offals'.

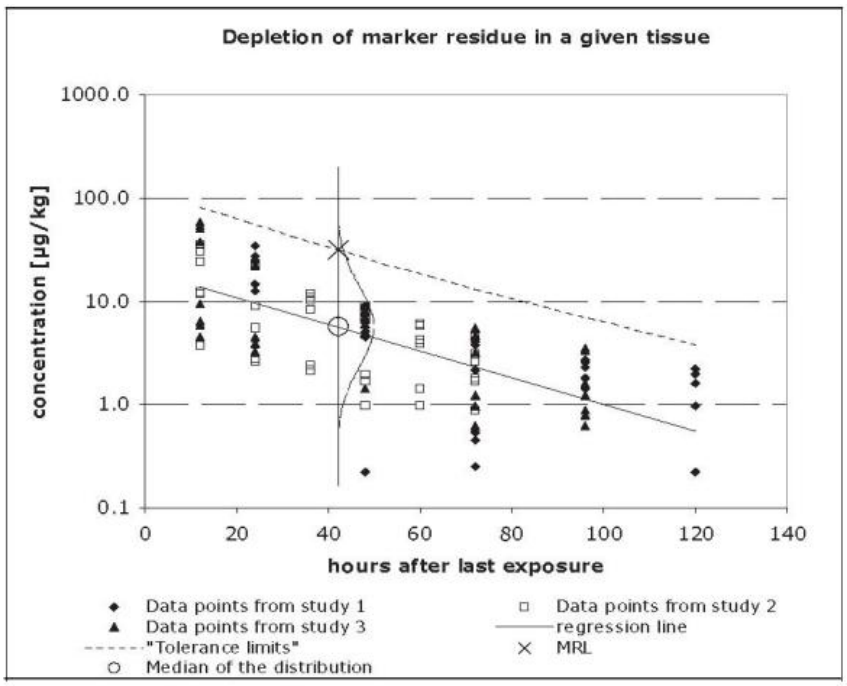
Further information on the median residue approach:

The median residue approach approximates the established EDI approach.

The 2006 JECFA report for the 66th meeting defines the link between the MRL and median residue concentration as follows:

'The MRL and the median concentration are derived from the same timepoint of the depletion data of the marker residue. The MRL is a point on the curve describing the upper one-sided 95% confidence limit over the 95th percentile. The median is the corresponding point on the regression line for the same time point. Both figures are obtained from a statistical evaluation of the data'.

This relationship between MRL and EDI is illustrated here (from JECFA66 report):



Explanation of the relationship between MRL and the median concentration used for the calculation of the estimated daily intake (EDI)

Second list of questions for the EWG:

1. There is a concern that extrapolated MRLs may not solve the issues that they were instigated to address. This could be in the case where residues of a veterinary drug substance in 'other edible offals' are consistently analysed to be above the extrapolated MRL, even where veterinary drugs are used in accordance with Good Veterinary Practice (GVP). This could lead to a reduction of consumer confidence in established MRLs, as well as cause issues with trading partners. The ramifications of this should be considered and hopefully addressed before the EWG recommends an approach to CCRVDF. One possible approach is to rename the extrapolated number so that it is an 'Action Level', rather than an MRL, and to write a guidance document on how exceedance of these action levels may be considered by those receiving such goods (see Annex 2 for details).
    a. Do you agree that using Action Levels would be more practical than the status quo?
    b. Can you agree that the proposed 'Action Level' approach should be followed? (The proposal would form part of the recommendation to CCRVDF; the guidance document would need to be developed after agreement at CCRVDF.)
    c. Can you propose a different approach that could overcome the fundamental concern?
2. In principle, can you agree to this list of conditions for extrapolation to 'other edible offals'?
    - Extrapolations will be conducted only when compounds are added to the priority list upon request from a Member.
    - Due to the lack of data available to CCRVDF, a call for relevant distribution and residues depletion data would be made at this point.
    - The extrapolated MRL will cover all 'other edible offals'. No refinement will be made for specific 'other edible offals'.
    - For dual use substances, where CCPR have already established an MRL for 'other edible offals', the EWG will recommend those established MRLs to CCRVDF to have them incorporated into published veterinary drug listings.
    - Extrapolations to 'other edible offals' can only occur within the same species.
    - Extrapolation to 'other edible offals' cannot be based on MRLs that have themselves been established by extrapolation.
    - These criteria are for extrapolation to 'other edible offals' only. They cannot be used to extrapolate to any other edible tissues or commodities.
3. In principle, can you agree to the proposed calculation criteria (see box)?
4. If there were relevant data available in a species that was not the species for which the extrapolation was requested, could these be used to reassure the EWG that the proposed MRL would likely be adhered to under GVP? How could that work?
5. Do you have any experience of using the extrapolated MRLs for 'other edible offals' established using the CCPR approach? If so, could you provide further details?
6. Do you have any further concerns or comments?

Round 2:

Question 1: There is a concern that extrapolated MRLs may not solve the issues that they were instigated to address. This could be in the case where residues of a veterinary drug substance in 'other edible offals' are consistently analysed to be above the extrapolated MRL, even where veterinary drugs are used in accordance with Good Veterinary Practice (GVP). This could lead to a reduction of consumer confidence in established MRLs, as well as cause issues with trading partners. The ramifications of this should be considered and hopefully addressed before the EWG recommends an approach to CCRVDF. One possible approach is to rename the extrapolated number so that it is an 'Action Level', rather than an MRL, and to write a guidance document on how exceedance of these action levels may be considered by those receiving such goods.

a. Do you agree that using Action Levels would be more practical than the status quo?

Member	Response	Chair's comments
Brazil	Yes. The use of Action Levels would be more feasible and operationally applicable than the current model based on MRL extrapolation, as it provides greater flexibility for risk management and helps reduce potential trade barriers, while maintaining consumer safety through a transparent and scientifically robust foundation.	The Chair thanks Brazil for these comments. It is agreed that flexibility is important in this example of extrapolation, as well as transparency.
Canada	Canada is not confident that changing the name from MRL to ooAL will alter the outcome with respect to trade and consumer confidence, should residues in other edible offal tissues consistently be detected when the veterinary drug is used according to GVP. However, Canada does believe that utilizing ooALs may provide some additional flexibility, as the approach outlined in Annex 2 recognizes that the values are not based on data and that residues exceeding an ooAL may not constitute a human food safety concern.	The Chair thanks Canada for these comments. The principle is agreed with, and it appears that the change of name is not a huge issue.
European Union	We support the concerns expressed in relation to the risk of establishing extrapolated MRLs for 'other edible offals'. We agree that the term 'MRL' should not be applied to extrapolated values for other edible offals. However, it is not clear to us how use of an alternative term, such as 'other offal Action Level' (ooAL), would address the concerns raised, particularly as guidance on the purpose and implementation approach for ooALs does not yet exist. We remain concerned that exporters of animal produce derived from animals treated in line with GVP will face great uncertainty in relation to whether or not their produce will be accepted, and that, consequently, the extrapolated values (whether termed 'MRLs' or 'ooALs') will cause difficulties for trade and reduce confidence in the Codex approach for setting limits for residues of vet drugs in food.	The Chair thanks the EU for these comments. It is agreed that the issues raised regarding exceedance of extrapolated MRLs/ooALs have not yet been addressed; it is the opinion of the Chair that creating guidance for those using the extrapolated MRLs/ooALs would be the next stage of this process. Additionally, it has been highlighted that the *status quo* does not provide any guidance; on this basis, the chair recommends that the EWG pushes forward with the updated proposed methodology for calculating the extrapolated MRLs/ooALs, with a request to CCRVDF to task the EWG with writing guidance to be used alongside them, in the next period.

Kingdom of Saudi Arabia	Saudi Arabia agrees that maintaining the current approach based on Maximum Residue Limits (MRLs) is more practical and scientifically sound than introducing the concept of 'Action Levels'. Replacing extrapolated MRLs with new terminology could create confusion. Instead, Saudi Arabia recommends strengthening the criteria for extrapolation and applying transparent, science-based calculation methods such as the TMDI model to ensure that extrapolated MRLs remain both realistic and protective of consumer health. In cases where occasional exceedances are observed under Good Veterinary Practice (GVP), these situations should be managed through clear guidance on interpretation and risk management rather than through changes in terminology.	The Chair thanks Saudi Arabia for these comments. Although there is some disagreement on what the extrapolated figures should be called (MRLs or ooALs), it is clear that there is support for using a transparent model to calculate extrapolated numbers, and for guidance to be created for those using those extrapolated numbers.
United States of America	In principle, the United States thinks that using Action Levels combined with a Codex Guideline could be more practical than the status quo. The Action Levels will provide competent authorities with a tool to make a quick, initial assessment (i.e., above or below). A complementary Codex Guideline would provide risk management recommendations and instruction on how to conduct a rapid risk assessment if the Action Level is exceeded. The Codex Guideline could also explain the differences between Action Levels and MRLs to not cause a reduction in consumer confidence.	The Chair thanks the USA for these comments. It is clear that establishing ooALs, with guidance to users is the preferred option for the USA.

b. Can you agree that the proposed 'Action Level' approach should be followed? (The proposal would form part of the recommendation to CCRVDF; the guidance document would need to be developed after agreement at CCRVDF.)

Member	Response	Chair's comments
Brazil	Brazil understands that the proposed 'Action Level' approach should be followed. Nonetheless, it is necessary to make a clear definition of guidelines for 'Action Level' adoption, making clear its use only for monitoring and control purposes and not for product registration.	It is clear that the concept of ooALs alongside guidance is Brazil's preference. It is agreed that these ooALs should not be used for product registration, and this should be made clear.
Canada	While Canada is not opposed to the approach outlined in Annex 2, Canada is of the opinion that the definition of ooAL should be revised to "A concentration of residue (expressed in mg/kg or µg/kg on a fresh weight basis) resulting from authorized use of a veterinary drug that is recommended by the Codex Alimentarius Commission to be recognized as acceptable in or on edible offal tissues other than liver and kidney, above which action **could** ~~should~~ be taken.". Canada believes that this change would allow flexibility, as it has been pointed out that residues that exceed the ooAL may not be a concern to consumer health.	The chair can agree with the proposal from Canada on this.

European Union	In the absence of clear agreement on how ooALs would be used, we cannot support the approach.	The chair considers that it will be for CCRVDF to give the EWG a mandate to create suitable guidance to be used alongside the 'ooALs'. It may not, therefore, be the right time to update the procedural manual until CCRVDF has agreed the supporting guidance.
Kingdom of Saudi Arabia		
United States of America	In principle, the United States thinks that developing other offal Action Levels combined with a Codex Guideline could represent a viable path forward for advancing the work on residues of veterinary drugs in other edible offal tissues.	The Chair agrees with the USA the proposed path forward is likely a viable one.
c. Can you propose a different approach that could overcome the fundamental concern?		
Member	**Response**	**Chair's comments**

Brazil

The approach presented would be suitable for evaluating the impact of adopting Action Levels for other offal if some modifications are made. To illustrate the need for some adjustments, we present an example below using the proposed methodology.

It can be anticipated that veterinary drugs whose estimated daily intake accounts for more than 90% of the upper bound of the ADI will necessitate the use of the EDI model instead of the TMDI approach. Tilmicosin is an illustrative example of this case.

Tilmicosin was evaluated by JECFA and in the dietary exposure assessment the intake estimated is higher than 90% of the upper bound of the ADI.

- Tilmicosin (ADI 0-40 µg/kg bw) – ADI upper bound (60 kg): 2400 µg/person per day. (In red colour the highest MRL and the lowest M:T).

Edible commodity	Daily consumption (kg)	MRL (µg/kg)	M:T	Amount per edible commodity (kg)
Muscle	0.3	100	0.50	60
Fat (mammals)*	0.05	100	0.50	10
Liver	0.10	1000	0.05	2000
Kidney	0.05	300	0.10	60
Sheep milk	1.5	50	0.50	150
Intake (µg/person):				2280

- Proposed calculations for MRL extrapolation:

Edible commodity	Daily consumption (kg)	MRL (µg/kg)	M:T	Amount per edible commodity (kg)
Muscle	0.3	100	0.50	60
Fat (mammals)*	0.05	100	0.50	10
Milk	1.5	50	0.50	150
Other edible offals	0.15	1000	0.05	3000
(adjusted) TMDI = Estimated total daily intake (µg/person):				= 3220

The daily intake represents 134% of the upper bound of the ADI, i.e., TMDI >ADI.

If TMDI > ADI, then the next highest established MRL would be used (as Xo) for 'other edible offals'

The next highest established MRL is 300 µg/kg (kidney). It is difficult to justify using this second-highest value, as there is a substantial difference between the highest and the second-highest MRLs.

Thanks to Brazil for providing this worked example. It certainly appears to be appropriate to use the EDI model, as this is the model JECFA uses.

Indeed, would it even be necessary to use the TMDI model first, if it were (and it seems to be) legitimate to use the EDI model where the TMDI model does not allow a suitable MRL/ooAL to be established?

The advantage of using the TMDI model is that it requires no further inputs than what is readily available in the public domain.

The data required for the EDI model may not be readily available in all cases.

If the EDI model is followed, and the highest MRL is always used for the extrapolation, as proposed here, this would still be protective of consumers; however, there is still the possibility of the extrapolated MRLs being exceeded and so guidance may still be required.

	Moreover, if the TMDI (Theoretical Maximum Daily Intake) still exceeds the ADI (Acceptable Daily Intake), it is recommended to apply the median residue or Estimated Daily Intake (EDI) approach, as commonly adopted by JECFA. Considering that JECFA concluded the median residue concentration to be the most appropriate estimate of long-term average exposure, given that residue levels in edible tissues varies daily, and reaffirmed the use of median values from depletion studies, adjusted for the marker-to-total residue ratio, when estimating chronic dietary exposure, Brazil recommends using the EDI model instead of the TMDI for these calculations. This approach provides a more realistic estimate of exposure and avoids unnecessarily conservative assumptions and calculations. We also believe that it is necessary to always use the highest MRL as the reference for calculation, since 'other edible offals' consist of tissues with very different physicochemical characteristics. Furthermore, there is no scientific justification to refine the calculation using the second highest MRL. For example, doramectin, a highly lipophilic compound with strong affinity for plasma lipoproteins, presents the highest MRL in fat, which likely represents more accurately the expected residue level in the brain, since this tissue is predominantly composed of lipids and allows greater diffusion of lipophilic substances. In contrast, oxytetracycline, a hydrophilic molecule with low logP and high affinity for divalent cations, tends to concentrate in liver and kidney, tissues with high perfusion and involved in metabolic and excretory processes. These examples illustrate that the distribution and persistence of residues depend strongly on the lipophilicity and pharmacokinetic behavior of each drug, supporting the rationale that the highest MRL provides the most appropriate and protective reference when extrapolating or deriving Action Levels for other edible offals. In conclusion, Brazil believes that to evaluate the impact of the adoption of the Action Level, the approach presented is appropriate if the median residues concentration is used and if the tissue to represent the other edible offals is always the one that has the highest MRL. In order to establish the Action Level for other edible offal, the most pragmatic approach is to assume the same value of the highest MRL, if the exposure assessment proposed previously does not exceed the ADI.	

Canada	Canada is not necessarily convinced that numerical values are required to address residues in other edible offal. Rather, a Codex guideline outlining how competent authorities could deal with such residues may serve as a better alternative.	This is an interesting approach and worth consideration. It is not clear how CODEX could provide such guidance without some kind of reference numbers to go by. Perhaps a general approach would be more useful to those in the field? Perhaps it could be recommended that the highest established MRL should be used, similar to the proposal from Brazil, but without having them codified. However, it has been agreed by CCRVDF that there should be some kind of confirmation that consumer safety can be assured.
European Union	We are not able to make specific proposals. However, we consider that some level of data (the nature of which would require discussion and agreement) would be needed to provide assurance that application of VMPs in line with GVP is unlikely to lead to noncompliant residue findings.	Indeed, this needs discussion.
Kingdom of Saudi Arabia		
United States of America	No, not at this time.	Noted.

Question 2: In principle, can you agree to this list of conditions for extrapolation to 'other edible offals'?

- Extrapolations will be conducted only when compounds are added to the priority list upon request from a Member.
- Due to the lack of data available to CCRVDF, a call for relevant distribution and residues depletion data would be made at this point.
- The extrapolated MRL will cover all 'other edible offals'. No refinement will be made for specific 'other edible offals'.
- For dual use substances, where CCPR have already established an MRL for 'other edible offals', the EWG will recommend those established MRLs to CCRVDF to have them incorporated into published veterinary drug listings.
- Extrapolations to 'other edible offals' can only occur within the same species.
- Extrapolation to 'other edible offals' cannot be based on MRLs that have themselves been established by extrapolation.
- These criteria are for extrapolation to 'other edible offals' only. They cannot be used to extrapolate to any other edible tissues or commodities.

Member	Response	Chair's comments
Brazil	Brazil does not agree with the following "For dual use substances, where CCPR have already established an MRL for 'other edible offals', the EWG will recommend those established MRLs to CCRVDF to have them incorporated into published veterinary drug listings". Brazil understands that the incorporation of MRL defined by CCPR would not be appropriate, considering the difference between the intake of certain substance in feed as a contaminant and used as a veterinary drug.	Agreed, this could lead to regular exceedances where no consumer safety issue arises. It is understood that in the case of dual use substances, there would be a discussion between the CCPR and CCRVDF to agree on common MRLs.
Canada	Yes.	Noted.

European Union	Question 2 relates to specific aspects of the methodology. While we have provided responses to these specific questions, our fundamental concern, as expressed in response to Q1, remains. Consequently, the responses below are really only relevant assuming this fundamental concern can somehow be addressed. • We agree that extrapolations should only be conducted following addition of compounds to the priority list. • We note that the criteria currently proposed (in the box beneath this table) do not include or make reference to data obtained as a result of a call for data. Clarity is needed on how such data would be used. As noted in our response to Q1c, we consider that some data should be available to provide assurance that the recommended limits would not lead to noncompliant residue findings when VMPs are used according to GVP. A call for data could be aimed at providing this assurance. However, discussion and agreement is needed on the nature and level of data that would be needed. Consequently, we may support a call for data, but only once agreement has been reached on what data is needed. • As a starting point, we agree that CCRVDF should be aiming to establish a single limit for 'other offals'. However, we are aware that the picture may be complicated as some substances do distribute preferentially to specific 'other offal' tissues (eg, ractopamine to lung). Discussion and agreement is needed in relation to how such scenarios would be dealt with. • As noted by the chairs in their accompanying document, the CCPR values have been established at levels that are appropriate based on exposure of animals to the relatively low levels of drugs that occur in pesticide-treated plants. We are not aware of any evidence to indicate that these residue levels are reflective of those that occur in animal produce following application of therapeutic levels of drugs directly to animals. While we support the need for harmonisation across CCPR and CCRVDF, we should be sure of the appropriateness of the values before including them in vet drug listings. Consequently, at this time, we do not support incorporation of established CCPR limits for 'other edible offals' into published veterinary drug listings. • We agree that extrapolation to 'other edible offals' should occur within the same species. • We agree that extrapolated MRLs should not be based on MRLs that have, themselves, been extrapolated. • We agree that the criteria under discussion only relate to extrapolation to 'other edible offals' and not to other tissues or commodities.	The concerns of the EU are recognised. The complications of this task are well highlighted. It is agreed that the EWG should establish what data would be useful to achieve the goal of assurance of consumer safety, although it has been established that there could well be exceedances of extrapolated MRLs/ooALs even where veterinary drugs are used according to GVP. TRR/distribution data in the target animal species might be the ideal, but what other data could be used and what assurance would they provide? This is a point that needs further discussion. It is agreed that all 'other edible offals' are not equal in terms of the distribution and retention time of residues of veterinary drugs, as described in the comments from Brazil. This is a point that needs further discussion. It is agreed that CCRVDF should not automatically harmonise with CCPR MRLs without a discussion between CCPR and CCRVDF.

Kingdom of Saudi Arabia	Saudi Arabia agrees in principle with the proposed conditions for extrapolation to "other edible offals," as they provide a practical and transparent basis for developing science-based MRLs. Saudi Arabia also considers that adherence to these criteria will help maintain consistency, support the continued use of MRL terminology rather than "Action Levels," and promote confidence in the Codex framework.	Noted.
United States of America	• Extrapolations will be conducted only when compounds are added to the priority list upon request from a Member. The United States agrees with this statement. • Due to the lack of data available to CCRVDF, a call for relevant distribution and residues depletion data would be made at this point. The United States agrees with this statement in principle. For clarity, the United States suggests indicating that the call for any relevant data will be made after a compound has been added to the priority list. • The extrapolated MRL will cover all 'other edible offals'. No refinement will be made for specific 'other edible offals'. In general, the United States agrees with this statement. However, if specific other offal tissue data are available, it might be possible and necessary to refine the tissue to which the extrapolated value applies. • For dual use substances, where CCPR have already established an MRL for 'other edible offals', the EWG will recommend those established MRLs to CCRVDF to have them incorporated into published veterinary drug listings. The United States is unsure whether this is necessary because the standard would already exist in the MRL database and be available for use. End users are unable to know whether a detected residue comes from pesticide or veterinary use. • Extrapolations to 'other edible offals' can only occur within the same species. The United States agrees with this statement. • Extrapolation to 'other edible offals' cannot be based on MRLs that have themselves been established by extrapolation. The United States agrees with this statement. • These criteria are for extrapolation to 'other edible offals' only. They cannot be used to extrapolate to any other edible tissues or commodities. The United States agrees with this statement.	The proposal to clarify that CCRVDF would put out a call for data only where a substance is on the priority list can be agreed. The Chair recognises the position of the USA regarding extrapolation to specific tissues (if the data are available); however, the remit of the EWG is to establish MRLs for 'other edible offal', without distinction. It is the opinion of the chair that the further refinement would add to the complexity of the task. This should be a point of discussion. It is agreed that CCRVDF should not automatically harmonise with CCPR MRLs without a discussion between CCPR and CCRVDF.

Question 3: In principle, can you agree to the proposed calculation criteria (see box)?		
Member	**Response**	**Chair's comments**
Brazil	Brazil agrees partially as explained above. It is important to emphasize that this assessment is for consumer safety, import and export purposes. It should not be used as a limit for product registration purposes, for example. It is worth noting that the scope of the calculation is solely for exposure analysis and is not applicable to control and monitoring issues for trade. In this case, we believe it would be more appropriate to use the value of the highest MRL already defined among matrices of the same species as the "Action Levels for other edible offals" which will be discussed in response to item 1.	It is agreed that the establishment of MRLs/ooALs for other edible offals is to allow for import/export and to assure consumer safety. It is not clear what is meant by 'not applicable to control and monitoring for trade', but if it is meant that domestic monitoring for assurance for trading partners (i.e. a part of the domestic residues control plan), then this can also be agreed.
Canada	Canada is in agreement with the proposed calculation criteria, with the exception of the daily consumption value proposed for other edible offal (i.e., 150 g). Canada is of the opinion that the consumption value should be based on available consumption data. As such, Canada is supportive of using a consumption value of 100 g, as previously proposed by the United States.	Although the chair is aware that the available consumption data may not be fully representative of all demographics, these are the only data available.
European Union	Question 3 relates to the specifics of the methodology. We consider that the proposed approach represents an appropriate way to calculate residue levels in 'other offals' that would not represent a consumer safety concern. However, in line with the comments made in response to Q1, we do not consider that this is a sufficient basis upon which to establish MRLs or 'ooALs'.	Noted.
Kingdom of Saudi Arabia	Saudi Arabia agrees in principle with the proposed calculation criteria. The approach provides a transparent, science-based, and stepwise methodology that links extrapolated MRLs with dietary exposure assessment. By applying the lowest M:T ratio and using an adjusted food basket in combination with the TMDI model, the method ensures conservative and harmonized evaluation of consumer safety. Saudi Arabia also supports the inclusion of the median residue approach as an additional refinement in cases where the initial TMDI calculation exceeds the ADI. This stepwise process provides flexibility while maintaining scientific robustness.	Noted.

United States of America	As written, the United States cannot agree to the proposed calculation. The United States continues to propose a 100 g consumption factor for other edible offal, which is a conservative estimate derived from data in the CIFOCOss database, JECFA's advice on how to select the highest reliable percentile, and the GEMS Food Cluster Diets database. A 150 g consumption factor for other edible offal has been proposed. The United States seeks to understand what consumption data were used to derive this value in light of the data referenced above which indicates 100 g is conservative. The proposed calculation uses a 0.09 kg consumption factor for poultry fat. The United States seeks clarification on this number, as the standard TMDI model uses 0.05 kg for fat regardless of species. The proposed calculation calls for considering the next highest MRL for extrapolation if a TDMI calculation exceeds the ADI, and to consider refinement of the exposure model (e.g., use median residue data if available) only after TMDI calculations for all MRLs exceed the ADI. The United States suggests refining the model, if possible, before moving to the next highest MRL if the initial TMDI calculation exceeds the ADI. This is consistent with Codex Guidelines established by CCFA.	The points of the USA are noted. The proposed amendment of the consumption factor from the Chair was to harmonise more with the standard food basket and as such does not have any concrete data behind it. The data from the CIFOCOss database in the area of 'other edible offals' are rather sparse, as noted, and thus may not be as conservative as they look. Nonetheless, these are the only data available and so the chair can agree to the change to 100 g in light of comments from USA and Canada. The Chair apologises for using the wrong version of the foodbasket. The USA is correct that the standard CODEX food basket does not discriminate between fats of different species. This will be corrected. The chair can agree to the approach proposed of refining the model before moving to the next highest MRL.

Question 4: If there were relevant data available in a species that was not the species for which the extrapolation was requested, could these be used to reassure the EWG that the proposed MRL would likely be adhered to under GVP? How could that work?		
Member	**Response**	**Chair's comments**
Brazil	No further comments.	Noted.
European Union	We consider that some data would be needed to provide assurance that the extrapolated values would be adhered to under GVP. We are open to the possibility that data obtained from species other than the target animal species may be sufficient to provide this reassurance. Some considerable discussion/experience is likely to be needed in order to establish the level of data needed. As a starting point, it may be appropriate to say that, if data were available demonstrating comparable ADME in a mammalian target species and in a second mammalian species, then residue levels seen in 'other offals' in the second mammalian species could be used to guide a decision on the extrapolation of MRLs/ooALs in the target species. However, discussion would be needed in relation to which and/or how many 'other offal' tissues data would be needed for.	Noted
Kingdom of Saudi Arabia	Yes, Saudi Arabia agrees that relevant data from a different species could be considered as supporting information to reassure the EWG that an extrapolated MRL would likely be adhered to under Good Veterinary Practice (GVP). However, such data should not replace species-specific information and must be interpreted with caution. Saudi Arabia recommends that any use of cross-species data should: • Be clearly identified as supportive evidence only, not the primary basis for establishing an MRL. • Take into account differences in physiology, metabolism, and tissue distribution between species. • Be incorporated, where appropriate, as part of a stepwise refinement to reduce uncertainty and strengthen confidence in the extrapolated value.	Noted
United States of America	The United States thinks this could be possible on a case by case basis. In general, data in another species (e.g., laboratory rodents) could provide a certain level of confidence about the distribution pattern of residues in tissues.	Noted.

Question 5: Do you have any experience of using the extrapolated MRLs for 'other edible offals' established using the CCPR approach? If so, could you provide further details?		
Member	**Response**	**Chair's comments**
Brazil	Brazil stated that it has no prior experience with this type of extrapolation. However, in response to the Kick-off message 1, we believe that our initial proposal was misinterpreted. In fact, Brazil proposed the adoption of the CCPR/JMPR approach or methodology to extrapolate MRLs to other edible offals. We did not propose that MRLs established by the CCPR/JMPR should be directly applied to other edible offals when the molecule is used as a veterinary drug. For example, if a molecule already has an MRL established by JECFA for liver or kidney matrices, the higher of these MRL should be used for extrapolation purposes. At the time, Brazil emphasized that adopting the CCPR/JMPR approach for extrapolation to other edible offals would be a more pragmatic, simple, appropriate, and internationally recognized solution. Notwithstanding the original proposal, Brazil now supports the approach presented in response to the questions under item 1.	Noted
Canada	No.	Noted
European Union	We do not have such experience.	Noted
Kingdom of Saudi Arabia	No response.	
United States of America	The United States does not have experience with using the CCPR approach for residues of veterinary drugs in other edible offal tissues.	Noted.

Question 6: Do you have any further concerns or comments?		
Member	**Response**	**Chair's comments**
Brazil	No further comments.	Noted.
Canada	Canada would like to reiterate the concerns highlighted by the European Union during the first round of comments. Canada's primary concerns are that 1) should GVP lead to exceedance of extrapolated MRLs for other edible offal, the validity of the position that Codex MRLs ensure consumer safety could be questioned, and 2) adopting an approach that could actually create difficulties for international trade and unfairly penalise products and producers that have used veterinary drugs according to GVP is not appropriate or acceptable.	Agreed.
European Union	Given the complexity of this project, CCRVDF could consider selecting 2 or 3 pilot substances for the EWG to work on. The EWG could search the literature for relevant pharmacokinetic and residue data in offal tissues and consider how these could be used to derive extrapolated limits. This exercise might provide a framework for the EWG to address questions on the nature and level of data needed.	Agreed. Will add this to the proposal.
Kingdom of Saudi Arabia	Saudi Arabia would like to emphasize that the CCPR approach to extrapolation can provide a useful point of reference. However, caution is needed since pesticides differ significantly from veterinary drugs in terms of dosage, exposure pathways, and metabolism. For this reason, the CCPR methodology should not be applied directly to veterinary drug residues without appropriate adjustments. At the same time, Saudi Arabia highlights that where CCPR has already established MRLs for "other edible offals" for dual-use substances, CCRVDF should adopt those values to ensure international alignment and avoid duplication of work. This approach would allow CCRVDF to benefit from existing Codex outputs while maintaining scientific rigor in veterinary drug evaluations.	Noted; however, see comments from Brazil (Q5).
United States of America	None at this time.	Noted.

Appendix III:

LIST OF PARTICIPANTS

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Veterinary Medicines Directorate

Co-Chair
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Heilyn Fernández Carvajal

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