



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

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REPORT OF THE PHYSICAL WORKING GROUP ON EXTRAPOLATION OF MRLS FOR VETERINARY DRUGS TO EDIBLE OFFAL TISSUES OTHER THAN LIVER AND KIDNEY

(Prepared by the Physical Working Group chaired by the United Kingdom)

INTRODUCTION

1. The United Kingdom chaired the Physical Working Group (PWG) on the extrapolation of MRLs for veterinary drugs to edible offal tissues other than liver and kidney. The Chair presented the current progress of the Electronic Working Group (EWG), which was chaired by the United Kingdom, and Co-Chaired by Costa Rica – summarising EWG comments, conclusions and outstanding issues on the topic.

INFORMATION PRESENTED TO THE PWG

2. The PWG was attended by various Member countries, organizations and observers, and the PWG Chair presented the outcomes of the discussion document that was shared as part of CX/RVDF 26/28/8.
3. The Chair presented the background, Terms of Reference (ToR) and limitations of the work. The EWG was re-established at CCRVDF27, with the UK assuming the Chair role and Costa Rica continuing as Co-Chair. Revised Terms of Reference (ToR) were agreed at CCRVDF27, which proposed two main strands of work: addressing Codex Members' requests for extrapolation of existing MRLs to additional species and developing criteria for extrapolation to other edible offals. The EWG commenced in March 2025, with two rounds of additional discussions conducted via the Codex Forum and focused primarily on the latter strand of work. It was explained that the work builds on the agreed JECFA definition of edible offals, with "other edible offals" defined as edible offals other than liver and kidney.
4. The three main recommendations from the EWG, as provided in **Appendix I**, were presented by the Chair.

SUMMARY OF CHANGES TO RECOMMENDATIONS FROM PWG

5. On Recommendation 1: Criteria to establish MRLs to edible offal tissues other than kidney and liver.
6. Point 1.1: To establish the following general conditions for extrapolation of MRLs to 'other edible offals'.
 - a. On point 1.1.c) – "The extrapolated MRL will cover all 'other edible offals'. No refinement will be made for specific other edible offals". The Chair proposed one general reference level for the group of other edible offals, and no disagreement was received on this suggestion. This question may be resolved by future work.
 - b. Agreement was reached to remove 1.1.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." on the basis that it is irrelevant and competent authorities may use these values in a way that works for them.

- c. Agreement was not reached on 1.1.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.” as it pertains to the nomenclature of the levels.
7. Point 1.2: To use the following process to determine the MRL to be extrapolated to ‘other edible offals’.
- a. One Member sought inclusion of the reference to liver and kidney in the text featuring in the paragraph in 1.2, which currently reads “The highest MRL previously established in the requested species will be put through the calculation first (proposed MRL to extrapolate, X_o). It was agreed to include reference to all the four standard edible tissues (liver, kidney, fat (skin/fat) and muscle).
8. Point 1.3: To recommend that the EWG undertakes future work as follows.
- a. Full consensus was not reached on whether c) “To establish guidance for stakeholders on the utilisation of the extrapolated MRLs (or ooALs), to focus on cases where they may be exceeded.” should remain or be removed from the text. Members raised views both for and against the need for guidance on the matter, with discussions centring around whether a) the need for guidance was premature b) whether there are merits of retaining it, and/or whether c) it be removed and potentially require separate discussion later.
 - b. The recommendation of the Chair was that the EWG conducted a pilot on 2-3 substances to establish whether guidance would be useful.

SUMMARY OF DISCUSSION ON OTHER KEY ISSUES

- 9. **Confirmation of what Members want extrapolated values to achieve.** The Chair sought clarity on the fundamental purpose of extrapolated values: discussions were had on whether these levels are intended to function as true MRLs, provide pragmatic assurance under GVP, or avoid zero tolerance outcomes in the absence of data. It was discussed that the original intent of these levels was to prevent trade issues.
- 10. **What the extrapolated other edible offal levels could be called, and why it matters.** There was no consensus reached by the PWG on nomenclature. Options included extrapolated MRLs, Action Levels or new terms (e.g. Reference Levels, or Offal Residue Levels). The Codex Secretariat highlighted that naming is not purely semantic: it affects legal interpretation, harmonisation, enforcement expectations, and alignment with Codex principles.
- 11. **On confirmation of consumer safety and data limitations.** Members acknowledged challenges in confirming consumer safety due to limited distribution and residue data for other edible offals. While safety can be inferred, confidence is constrained by data gaps. The good work presented by the Republic of Korea during the side-event was highlighted as the type of evidence which could be beneficial for such an assessment. The idea of a pilot for compounds such as ivermectin and tetracyclines, as proposed by the Chair and supported by several Members, was seen of potential benefit.
- 12. **On residue intake calculations.** One Member proposed considering acute reference dose (ARfD) due to potentially higher offal consumption but lacked supporting data. After discussion, consensus was reached to retain 100 g/day for chronic exposure, while acknowledging that substances with an ARfD may warrant future acute exposure consideration. The Chair concluded that this could be put forward as a proposal for future work, at the next opportunity.

CONCLUSIONS AND NEXT STEPS (FOR PLENARY)

- 13. Codex Members and Observers are invited to consider:
 - i. The amendments to the Recommendations as presented above, which are outlined fully in **Appendix I**.
 - ii. The discussion points on the key issues, above.
 - iii. Proceeding with the Chair’s suggestion of a pilot, to help in ironing out issues.

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 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 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)h) 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. Decision on what to call the extrapolated values should be considered as part of a pilot, using the proposed calculation criteria below.~~

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 (from one of liver, kidney, fat (skin/fat), or muscle) 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)	<u>Residue exposure concentration</u> 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)	Yf	0.05*Xf/Yf
Milk	1.5	Established MRL, <u>or use median residue (EDI)</u> (Xmi)	Ymi	1.5*Xmi/Ymi

Eggs	0.1	Established MRL, or use median residue (EDI) (Xe)	Ye	$0.1 * X_e / Y_e$
Honey	0.05	Established MRL, or use median residue (EDI) (Xh)	Yh	$0.05 * X_h / Y_h$
Other edible offals	0.1	Proposed MRL to extrapolate (Xo)	Lowest of all established M:Ts in liver, kidney, fat and muscle. (Yo)	$0.1 * X_o / Y_o$
(adjusted) TMDI = Estimated total daily intake ($\mu\text{g}/\text{person}$):				= 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. [Median levels would also be used for milk, eggs, and/or honey, if MRLs are already established for these commodities.](#)
- 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:

- 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).
- 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).
- To [consider whether there is a need to](#) establish guidance for stakeholders on the utilisation of the extrapolated [MRLs \(or ooALs\) values](#), 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~~ (To be decided) = A concentration of residue (expressed in mg/kg or $\mu\text{g}/\text{kg}$ 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.
- [Edible offals = Those parts of an animal, apart from the skeletal muscle, fat, and attached skin, that are considered fit for human consumption.](#)
- '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 – LogPow,
 - 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 values](#) 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 [consider whether there is a need to](#) create guidance on how to use the extrapolated figures for those in the field.