



JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
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REPORT OF THE WORKING GROUP ON THE PRIORITY LIST OF VETERINARY DRUGS
REQUIRING EVALUATION OR RE-EVALUATION BY JECFA

Introduction

The physical working group (PWG) on the priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA was held on February 12, 2023, and chaired by James Deller (Australia). The Chair reminded the EWG on the prioritization criteria and advised the PWG that document CX/RVDF 23/26/11 had been prepared for CCRVDF26 to communicate comments received in response to circular letter CL 2022/72-RVDF issued in October 2022.

Part I. Veterinary drugs for inclusion in the Priority List for JECFA evaluation / re-evaluation

1. Amoxicillin: The request was for MRLs to be established for chicken tissues. Amoxicillin has previously been evaluated by JECFA and an ADI and ARfD set. The nominator, Chile, confirmed residue depletion data and validated analytical methods are being generated for evaluation by JECFA and should be available by July 2024. The working group recommended that amoxicillin should be included on the priority list.
2. Clopidol: The request was for an ADI to be established along with MRLs for chicken tissues. The nominator, Republic of Korea, confirmed that data (toxicological, residue depletion and analytical methodology) should be available by July 31 2023. The working group recommended that clopidol should be included on the priority list.
3. Fumagillin: The request was for an ADI to be established along with MRLs for honey and fish meat. The nominator, Republic of Korea, confirmed that data (toxicological, residue depletion and analytical methodology) should be available by September 30 2023. The working group recommended that fumagillin should be included on the priority list.
4. Norfloxacin, Doxycycline, Tylosine, Gentamycin, Colistin, Trimethoprim and Ciprofloxacin: Ghana, in CRD12, nominated these compounds to the priority list but confirmed at the PWG that they do not have relevant data available. In the absence of data, the working group recommended that these compounds should not be included on the priority list. Members and observers were encouraged to consider if relevant data for these compounds could be made available prior to CCRVDF27.
5. Diminazene and Isometamidium: Senegal, at the PWG, nominated these compounds to the priority list but confirmed that they do not have relevant data available. In the absence of data, the working group recommended that these compounds should not be included on the priority list. Members and observers were encouraged to consider if relevant data for these compounds could be made available prior to CCRVDF27.

Recommendation 1: Approve amoxicillin, clopidol and fumagillin for inclusion on the priority list (see also Appendix 1).

Part II. Veterinary drugs for which data availability should be confirmed at next CCRVDF

6. Amoxicillin: While this compound was existing on Part II of the priority list, it was addressed in Part I. Amoxicillin therefore can be removed from Part II of the priority list.
7. Ethoxyquin: Following inclusion on the priority list at CCRVDF21 (2013), ethoxyquin has been retained on the priority list pending confirmation that data is available to enable an evaluation by JECFA. India indicated that data was being generated at CCRVDF25 but an update on the data generation was not received at the PWG, or in response to CL 2022/72-RVDF. As India were not present at the PWG to provide an update, the working group agreed to retain the compound on Part II of the priority list pending confirmation of data availability.
8. Norfloxacin: Norfloxacin was include on the priority list at CCRVDF25 (2021). Peru, in response to the CL 2022/72-RVDF, indicated that the request for toxicological data has been processed to support the evaluation of norfloxacin. As

Peru were not present at the PWG to provide a further update, the working group agreed to retain the compound on Part II of the priority list pending confirmation of data availability.

Recommendation 2: Approve the retention on ethoxyquin and norfloxacin on the Part II of the priority list as veterinary drugs for which data availability should be confirmed at CCRVDF27 (see also Appendix 1).

Part III. Veterinary drugs for which additional data/information is necessary to complete the JECFA evaluation

9. Imidacloprid: JECFA (94th meeting) was unable to reach a conclusion on an ADI or ARfD due to an outstanding question in relation to anti-microbial activity. Norway, in response to the CL 2022/72-RVDF, indicated that the Sponsor has the relevant data available for consideration by JECFA. The working group recommended that imidacloprid should be included on the priority list.

Recommendation 3: Approve imidacloprid for inclusion on the priority list (see also Appendix 1).

10. Ethion: JECFA (85th meeting) requested additional data/scientific argument to enable MR and MR:TRR to be determined and analytical methodology. At the PWG, Argentina indicated that data generation has been delayed but is expected to be completed by CCRVDF27. The working group agreed to retain the compound on Part III of the priority list pending confirmation of data availability.

11. Flumethrin: JECFA (88th meeting) requested additional data/scientific argument to enable MR and MR:TRR to be determined, residue depletion data, identity of metabolite in milk data and data relevant to the toxicological profile. An update on data availability was not received at the PWG, or in response to CL 2022/72-RVDF. As some delegations were not present at the PWG to provide an update, the working group agreed to retain flumethrin on Part III of the priority list pending confirmation of data availability.

12. Fosfomycin: JECFA (88th meeting) requested additional data/scientific argument to enable a mADI to be set, additional data/scientific argument to enable MR and MR:TRR to be determined and analytical methodology. An update on data availability was not received at the PWG, or in response to CL 2022/72-RVDF. As some delegations were not present at the PWG to provide an update, the working group agreed to retain fosfomycin on Part III of the priority list pending confirmation of data availability.

Recommendation 4: The meeting notes the updates on ethion, flumethrin and fosfomycin which are being considered by JECFA (see also Appendix 1).

Part IV. Parallel review – Evaluation of a new compound

13.. Selamectin: JECFA (94th meeting) concluded that MRL recommendations could not be made without full registration in a Member state, including GVP. It was confirmed at the PWG that national approval was still pending. The working group agreed to retain selamectin on Part IV of the priority list.

Recommendation 5: The meeting notes the update on the parallel review compound (selamectin) currently being considered by JECFA (see also Appendix 1).

Part V. Extrapolation

14. Jordan, Morocco, AIDMSO and IUFoST in CRD11 requested that CCRVDF consider the establishment of MRLs for finfish based on extrapolation for Deltamethrin, Flumequine, Lufenuron, Teflubenzuron, Emamectin Benzoate and Diflubenzuron. The working group noted that the potential for extrapolation to finfish had already been considered for Deltamethrin, Flumequine and, Teflubenzuron. The working group recommended that potential to extrapolate to finfish MRLs for Lufenuron, Emamectin Benzoate and Diflubenzuron should be included on the priority list under Part V Extrapolation.

Recommendation 6: Approve for Lufenuron, Emamectin Benzoate and Diflubenzuron for inclusion on the priority list under Part V Extrapolation (see also Appendix 1).

Name of Compound	Question(s) to be answered	Registration status	Proposed by	Comments	When will data package be available
PART I: Veterinary drugs for inclusion in the Priority List for JECFA evaluation / re-evaluation					
Amoxicillin	Request for MRLs for chicken muscle, skin/fat, liver and kidney.	Nominator noted that relevant registrations exist in the European Union, Canada and Chile.	Chile	ADI set by JECFA at 0-0.07 µg/kg bw (2011), ARfD 0.005 mg/kg bw (2017). Classified by WHO as a CIA and by the OIE as VCIA.	Residue data is expected to be available July 2024.
Clopidol	The request is for an ADI to be established for clopidol along with MRLs for chicken muscle, fat, liver and kidney.	Nominator noted that clopidol is registered in the Republic of Korea.	Republic of Korea	Clopidol has not been assessed by JECFA. A toxicological and residues dossier is required.	Residue and toxicological data is expected to be available July 31, 2023.
Fumagillin	The request is for an ADI to be established for fumagillin along with MRLs for honey and fish	Nominator noted that fumagillin is registered in the Republic of Korea.	Republic of Korea	Fumagillin has not been assessed by JECFA. A toxicological and residues dossier is required.	The majority Residue and toxicological data is expected to be available July 31, 2023 with exception of a trout depletion study which is expected September 30, 2023.
Imidacloprid	JECFA (94 th meeting) was unable to reach a conclusion on an ADI or ARfD due to an outstanding question in relation to anti-microbial activity.	Nominator noted that relevant MRLs are established in the EU.	Norway	JECFA (94 th meeting) considered imidacloprid toxicological and residues data but recommended that further data relevant to potential anti-microbial activity was required.	Requested data is currently available.

Part II. Veterinary drugs for which data availability should be confirmed at the next CCRVDF				
Name of Compound	Question(s) to be answered	Proposed by	Comments	When will data package be available
Amoxicillin	See Part I above			
Ethoxyquin (feed additive use)	Request to establish MRL in shrimp muscle.	Philippines/India	Carried over from CCRVDF21 (2013). ADI 0-0.005 mg/kg bw (2005 JMPR). The ADI and the ARfD are applicable to ethoxyquin and its metabolites/degradation products methylethoxyquin (MEQ), dihydroethoxyquin (DHEQ), dehydrimethylethoxyquin (DHMEQ) ARfD 0.5 mg/kg bw (2005 JMPR).	No Update provided to the PWG.
Norfloxacin	Request to establish MRLs for cattle, camelids, equines, goats, poultry, sheep and swine tissues.	Peru	Norfloxacin is classified by WHO as a CIA and by the OIE as a veterinary CIA.	No Update provided to the PWG.
Part III. Veterinary drugs for which additional data / information is necessary to complete the JECFA evaluation				
Name of Compound	Information required by JECFA	Proposed by	Comments	When will data package be available
Imidacloprid	See Part I above			
Ethion	Additional data/scientific argument to enable MR and MR:TRR to be determined, analytical method.	Argentina (Costa Rica, Uruguay)	From JECFA (85 th meeting), ADI 0-0.002 mg/kg bw, ARfD 0.02 mg/kg bw for general population and 0.002 mg/kg bw for women of child-bearing age.	Metabolism studies to identify compounds of concern, validation of an analytical method and a radiolabel study to enable MR and MR:TRR to be determined are expected to be completed by CCRVDF27.

Flumethrin	Additional data/scientific argument to enable MR and MR:TRR to be determined, residue depletion data, identity of metabolite in milk and toxicological profile.	EU	ADI set by JECFA at 0-0.004 mg/kg bw (2017), ARfD 0.005 mg/kg bw (2017).	No update provided to the PWG.
Fosfomycin	Additional data/scientific argument to enable a mADI to be set, additional data/scientific argument to enable MR and MR:TRR to be determined, analytical method.	Argentina/Paraguay	JECFA (88 th meeting) could not establish an ADI.	No update provided to the PWG.
Part IV. Parallel review – Evaluation of a new compound				
Name of Compound	Information required by JECFA	Proposed by	Comments	When will data package be available
Selamectin	Confirmation of full registration in a Member state, including GVP.	Canada/US	National authority approval is still pending.	No date provided to the PWG.
Part V. Extrapolation				
Name of Compound(s)	Extrapolation to	Proposed by	Indication that extrapolation principles could be met	
Lufenuron, Emamectin Benzoate and Diflubenzuron	Finfish	Jordan, Morocco, AIDMSO and IUFoST	Yes	