



JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-third Session

Houston, Texas, United States of America, 17 – 21 October 2016

**REPORT OF IN-SESSION WORKING GROUP ON DRAFT PRIORITY LIST OF VETERINARY
DRUGS REQUIRING EVALUATION OR RE-EVALUATION BY JECFA**

I. Introduction

The in-session working group (WG) was held on October 17, 2016 and chaired by Dr Dugald MacLachlan (Australia) with Dr Vittorio Fattori / Dr Markus Lipp (FAO/JECFA Secretariat) and Dr Phillipe Verger (WHO/JECFA Secretariat) assisting. The Chair reminded the WG on the prioritization criteria, and the JECFA Secretariat emphasized the need for respecting the commitment to submit data in time.

II. New proposals for the priority List

1. Ethion: The request is for MRLs for cattle tissues. An ADI has been established by JMPR (1990) but it was noted that an updated toxicological review would be required. Residue data are available; residue depletion and method data. The working group recommended ethion should be retained on the priority list until the 24th Session of CCRVDF, at which time the availability of data should be confirmed or ethion should be then removed from the priority list.

2. Flumethrin: The request is for MRLs for honey. An ADI was established by JMPR in 1996 but it was noted that an updated toxicological review may be required. The sponsor confirmed that a complete data package will be available for January 2017. The JECFA secretariat noted flumethrin has been proposed by CCPR under its periodic review program for evaluation by JMPR in 2018. The working group recommended that flumethrin should be included on the priority list.

3. Fosfomycin (fosfomicina/ phosphomycin): The request is for MRLs for chickens and swine. The sponsor confirmed that a residue data package is currently available. Toxicology data were available in the form of an evaluation report by Japan. The JECFA secretariat confirmed that original data reports would be required. The working group recommended that fosfomycin should be retained on the priority list until the 24th Session of CCRVDF, at which time the availability of data should be confirmed or fosfomycin should be then removed from the priority list.

4. Halquinol: The request is for MRLs for swine tissues. The sponsor confirmed that a complete data package will be available for by the end of March 2017. The working group recommended that halquinol should be included on the priority list.

5. Lufenuron: The request was for an MRL for certain fish. The sponsor confirmed that a complete data package will be available for January 2017. Lufenuron was evaluated by the 2015 JMPR and an ADI established. The working group recommended that lufenuron should remain on the priority list.

6. Monepantel: the request is for MRLs for cattle tissues. The latest toxicological evaluation by JECFA was in 2012. Residue information will be available for December 2016. The working group decided to recommend that monepantel should be included on the priority list.

7. Triamcinolone (triamcinolona): The request is for MRLs for cattle, sheep, goat and swine tissues. The sponsor confirmed that residue data are available. Several delegations noted the importance of this substance. The JECFA secretariat noted a toxicological review would be required. The working group recommended triamcinolone should be retained on the priority list until the 24th Session of CCRVDF, at which time the availability of data should be confirmed or triamcinolone should be then removed from the priority list.

8. Bismuth subnitrate: The request was for an MRL for milk. The sponsor confirmed that a complete data package will be available the end of March 2017. The working group recommended that lufenuron should remain on the priority list.

9. Previously listed compounds:

- Amoxicillin: further clarification was requested on actual data availability. Korea has committed to provide method, residue, pharmacokinetic and monitoring data. JECFA last evaluated the toxicology of amoxicillin in 2011 setting an ADI of 0–0.7 µg/kg body weight on the basis of microbiological effects. The working group decided to retain amoxicillin in the priority until the 24th Session of CCRVDF, at which time the availability of data should be confirmed or amoxicillin should be then removed from the priority list.
- Ampicillin: MRLs were requested only in fish. As noted by the 23rd CCRVDF, there is no current ADI established by JECFA and data are currently lacking to establish ADI. It was therefore decided to retain ampicillin in the priority until the 24th Session of CCRVDF, at which time the availability of data should be confirmed or ampicillin should be then removed from the priority list.
- Ethoxyquin: No data are currently available for ethoxyquin, but the working group considered that it should be retained on the priority list until the 24th Session of CCRVDF, at which time the availability of data should be confirmed or ethoxyquin should be then removed from the priority list.
- Lufenuron: Updated submissions received and considered above as a new proposal

III. Interactions between JECFA and the Priorities Working Group

The JECFA Secretariat briefly reviewed the process for scheduling the evaluation of a substance once it is on the priority list. Issues faced by the JECFA Secretariat include:

- Difficulties to obtain firm commitments for data submissions with subsequent impact on efficient working of JECFA.
- JECFA resources are limited. JECFA needs the full cooperation of sponsoring member states and companies to provide data in a timely fashion; meetings may be cancelled if data does not arrive by the promised date.
- There is a need for a clear response to calls for proposals for the priority list, with no late submissions, and a need for more detailed information before a substance goes on the priority list.

IV. The working group made the following recommendation to the Committee:

1. approve the substances recommended in the accompanying table for inclusion on the priority list (Appendix 1).

Appendix 1

PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION OR RE-EVALUATION BY JECFA (PROPOSED)

Name of Compound	Question(s) to be answered	Data Availability / Timing	Proposed by	Comments	When will data package be available
PART A: Proposed for 2017 JECFA Meeting					
Bismuth sub-nitrate	Request for MRL for milk	Nominator notes has been evaluated by a number of countries	New Zealand		Full package available by end March 2017
Flumethrin	Request ADI and MRL establishment for honey		EU	ADI set by JMPR at 4 µg/kg bw (1996) Currently scheduled by CCPR for JMPR evaluation of tox in 2018	Full data package (tox and residue) will be available by January 2017
Halquinol	Request ADI and MRL establishment in swine tissues		USA		Data will be available by end March 2017 Full data package (tox and residue)
Lufenuron	Request ADI and MRL establishment in fin fish (salmon/trout) <i>muscle and skin in natural proportions</i>	Nominator notes that relevant MRLs are established in a number of countries.	Norway and Chile	Fin fish MRL established in EU. Lufenuron was evaluated by the 2015 JMPR which set an ADI (20 4 µg/kg bw) with ARfD unnecessary	Full data package (tox and residue) will be available by January 2017
Monepantel	Request MRL establishment in cattle tissues		New Zealand		Data will be available by December 2016 (Residue data)

Name of Compound	Question(s) to be answered	Data Availability / Timing	Proposed by	Comments	When will data package be available
Part B. Compounds for which data availability will be confirmed at the next CCRVDF					
Amoxicillin	Request MRL establishment in fin fish muscle and skin in natural proportions.	Nominator notes that relevant MRLs are established in a number on countries. Some data in public domain. IFAH members unable to provide data. Korea has method, residue, pharmacokinetic and monitoring data	Republic of Korea	JECFA ADI of 0–0.7 µg/kg body weight on the basis of microbiological effects (2011). MRLs established in EU for all food producing species. Classified by WHO as a CIA. Prudent use in animal husbandry recommended. Classified by OIE as a VCIA with comments including: This class is very important in the treatment of many diseases in a broad range of animal species; Few economical alternatives are available.	Republic of Korea to confirm data availability at 24 th CCRVDF.
Ampicillin	Request ADI & MRL establishment in fin fish muscle and skin in natural proportions	Nominator notes that relevant MRLs are established in a number of countries. Availability of sponsor data not clear. Some data in public domain. IFAH members unable to provide data. Republic of Korea has method, residue, pharmacokinetic and monitoring data	Republic of Korea	MRLs established in EU for all food producing species. Classified by WHO as a CIA. Prudent use in animal husbandry recommended. Classified by OIE as a VCIA with comments including: This class is very important in the treatment of many diseases in a broad range of animal species; Few economical alternatives are available.	No data to allow establishment of ADI. Leave on list, to be reconsidered at 24 th CCRVDF.
Ethion	Request MRL establishment for cattle tissues	Nominator notes that relevant MRLs are established in a number of countries. IFAH members unable to provide data. Argentina has method, residue, pharmacokinetic and monitoring data	Argentina/Uruguay	ADI set by JMPR at 2 µg/kg bw (1990). An updated toxicological review required	Residue data will be available by September 2016. Toxicological data required but availability uncertain. Data availability to be confirmed at 24 th CCRVDF

Name of Compound	Question(s) to be answered	Data Availability / Timing	Proposed by	Comments	When will data package be available
Ethoxyquin (feed additive use)	Request to establish MRL in shrimp muscle		Philippines	From RVDF21 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 data submitted in response to call for data. Data availability to be confirmed at 24 th CCRVDF
Fosfomycin (fosfomicina/ phosphomycin)	Request ADI and MRL establishment in chicken and swine tissues	Nominator notes that relevant MRLs are established in a number of countries.	Argentina/Paraguay	Classified by WHO as critically important antimicrobial in human medicine (CIA). Prudent use in animal husbandry recommended. Classified by OIE as highly important antimicrobial in veterinary medicine (VCIA) with comments: this antimicrobial is authorised only in a few countries. Fosfomycin has a limited number of alternatives in some fish infections. Critically important for fish.	Residue data available now but availability of toxicity data is uncertain. Data availability to be confirmed at 24 th CCRVDF
Triamcinolone (triamcinolona)	Request ADI and MRL establishment in cattle, sheep, goats and swine tissues	Nominator notes that relevant MRLs are established in Argentina and Brazil	Argentina	Need clarification as to availability of toxicology and metabolism data	Residue data available now but availability of toxicity data is uncertain. Data availability to be confirmed at 24 th CCRVDF
Part C. Continuing JECFA evaluations from 2016, for information					
Diflubenzuron	Toxicity data for 4-chloroaniline (PCA)				
Sisapronil	Additional data/scientific argument to enable ADI to be determined				

Name of Compound	Question(s) to be answered	Data Availability / Timing	Proposed by	Comments	When will data package be available
Zilpaterol	Data on relative bioavailability				
Part D Concern Forms and other General Considerations for JECFA					
		To be considered at the next JECFA meeting on veterinary drugs			