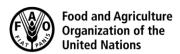
CODEX ALIMENTARIUS COMMISSION





Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item: 12 CRD₂

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

Twenty-fourth Session

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 April 22, 2018 and chaired by Dr Dugald MacLachlan (Australia). The Chair reminded the WG on the prioritization criteria and advised documents prepared for the CCRVDF24 that were relevant to the discussion (CX/RVDF 18/24/12, CX/RVDF 18/24/12 add1, CRD 13, CRD 15, CRD 20 and CRD 25).

II. New proposals for the priority List

- 1. Flumethrin: The request is for MRLs for cattle. An ADI of 0-0.004 mg/kg bw and ARfD of 0.005 mg/kg bw have been established by JECFA (2017). The sponsor confirmed that a complete residues data package is currently available. The working group recommended that flumethrin should be included on the priority list.
- 2. Fosfomycin (fosfomicina/ phosphomycin): At CCRVDF23, it was agreed fosfomycin should be retained on the priority list until CCRVDF24, at which time the availability of toxicity data should be confirmed or fosfomycin should be then removed from the priority list. The nominator has confirmed that toxicity data are now available and the working group recommended that fosfomycin should be included on the priority list.
- 3. Ivermectin: The request is for a reconsideration of the current MRLs for sheep and pigs noting the revised ADI (JECFA 2015). Codex MRLs are currently established for liver and fat only in pigs and sheep. It is proposed that MRLs should be established for the four tissues, fat, muscle, liver and kidney. The nominator confirmed that residue data are available in the four tissues for sheep with data soon to be available for pigs. The working group recommended that ivermectin should be included on the priority list.

4. Previously listed compounds:

- Ethoxyquin: At 23CCRVDF ethoxyquin was retained on the priority list pending confirmation at CCRVDF24 that data is available to enable an evaluation by JECFA else ethoxyquin should be then removed from the priority list. The working group was unable to consider ethoxyquin as the nominator was not present to provide the necessary advice.
- Triamcinolone (triamcinolona): The request is for MRLs for cattle, sheep, goat and swine tissues. CCRVDF23 agreed 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. As confirmation has been received that toxicological data necessary to complete an evaluation are not available, the working group recommended triamcinolone be removed from the priority list.

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

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

RVDF/24 CRD2

| Name of Compound | Question(s) to be answered | Data Availability / Timing | Proposed by | Comments | When will data package be available |
|---|---|---|--------------------|---|--|
| PART A: Proposed for 20° | 18 JECFA Meeting | | | · | |
| Flumethrin | Request for MRLs for cattle | Nominator notes that relevant MRLs are established in a number of countries. | EU | ADI set by JECFA at 0- 0.004 mg/kg bw, ARfD 0.005 mg/kg bw (2017) | Residue data package submitted to JMPR December 2017, can be transferred to JECFA |
| 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 CIA. Prudent use in animal husbandry recommended. Classified by OIE as 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 and toxicological data available April 2018 |
| Ivermectin | Request for reconsideration in MRLs for pigs and sheep/goats, MRLs requested in muscle, liver, kidney and fat | Nominator notes that relevant MRLs are established in Argentina. MRLs are established in a number of other countries. | Argentina | ADI set by JECFA at 0-10 µg/kg bw, ARfD 0.2 mg/kg bw (2015) | Residue data on sheep available June 2018, residue data on pigs to be generated |
| Part B. Compounds for w | nich data availability will be co | onfirmed at the next CCRVDI | <u> </u> | | |
| Ethoxyquin (feed additive use) | Request to establish MRL in shrimp muscle | | Philippines | From CCRVDF21 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. Philippines to advise if data are available, if not recommend delete from the priority list. |

RVDF/24 CRD2

| Part C. Continuing JECFA evaluations from 2016 and 2017, for information | | | | | | | |
|--|---|--|--|--|--|--|--|
| Diflubenzuron | Toxicity data for 4- chloroaniline (PCA) | | | | | | |
| Ethion | Additional data/scientific argument to enable MR and MR:TRR to be determined, analytical method | | | | | | |
| Halquinol | Additional data/scientific argument to enable ADI and MR:TRR to be determined | | | | | | |
| Sisapronil | Additional data/scientific argument to enable ADI to be determined | | | | | | |