



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

Minneapolis, Minnesota, United States of America, 26 – 30 August 2013

DRAFT AND PROPOSED DRAFT MRLs FOR VETERINARY DRUGS

Part 1 - DRAFT MRLS FOR MONEPANTEL AT STEP 6 (REP12/RVDF APPENDIX V)

Comments of Kenya, Nigeria, the Philippines and African Union (AU)

KENYA

Specific comments

According to the CL 2012/-23 Part A Kenya notes that 20th CCRVDF requested JECFA [scientific advisor] to evaluate the safety of a set of higher MRLs on Muscle 700 µg/kg, liver 5000 µg/kg, kidney 2000 µg/kg, fat 7000 µg/kg than originally recommended by JECFA. Kenya suggests keeping the draft MRLs at step 7 and considering their advancement after receiving JECFA's response.

NIGERIA

Specific comments

Nigeria notes JECFA's MRLs for Monepantel for Sheep- muscle, liver, kidney and fat and therefore supports the advancement of MRLs for Monepantel to the next Step.

Justification

The safety evaluation by JECFA was based on ratio of marker residue to total residue. However, JECFA is to provide the result of evaluation of the proposed higher MRLs.

PHILIPPINES

Specific comments

Monepantel (at Step 6)

The Philippines reiterates its position not to support the further advancement of the recommended draft MRLs for Monepantel. Resolution will be made until JECFA release its latest evaluation on the safety of the proposed higher MRLs for Monepantel as requested by CCRVDF during its 20th Session.

AFRICAN UNION (AU)

The proposed MRLs for Monepantel for sheep tissues (liver, kidney, muscle, fat) are acceptable; considering that the ADI has been determined at a safety factor of 100 and the EDI represents 17% of the upper bound of the ADI in mice.

The proposed MRLs for Monepantel for sheep tissues (muscle, liver, kidney, fat) should be advanced to step 6.

Part 2- PROPOSED DRAFT MRLS FOR APRAMYCIN AND DERQUANTEL AT STEP 4
(REP12/RVDF APPENDIX VI)

Comments of Kenya ,Nigeria, African Union (AU)

KENYA

General comments

- i. We accept the temporary MRLs recommended by JECFA for Apramycin in cattle and chicken kidneys at step 4 and noted JECFA's inability to recommend MRLs for the other tissues and species due to data limitation.
- ii. We accept the MRLs recommended by JECFA for Darquantel for sheep muscle, liver, kidney and fat. However, MRL for sheep milk should be held at step 4 until data is made available.

Specific comments

- I. MRLs for Apramycin for cattle and chicken kidneys should be held at step 4 until there is a validated analytical method for conducting depletion studies for other species and tissues.
- II. MRLs for Darquantel for sheep muscle, liver, kidney and fat to advance to step 5. MRL for sheep milk should be held at step 4.

NIGERIA

Specific comments

APRAMYCIN (antimicrobial agent)

Nigeria supports JECFA's opinion to keep the MRLs for Apramycin as temporary.

Justification

There are needs for more rigorous scientific data from improved analytical methods as requested by JECFA to provide scientific basis for advancing apramycin MRLs.

DERQUANTEL (antiparasitic gent)

Nigeria notes JECFA's MRL evaluation of derquantel MRLs for sheep; muscle, liver, kidney, fat and therefore supports advancement of the MRLs to the next step while that of sheep milk should still be retained at step until residue data are provided for milk.

Justification

Residue data in milk should be provided by the sponsor to enable JECFA fully evaluate and propose MRL in sheep milk.

AFRICAN UNION (AU)

Apramycin

African Experts accepted the temporary MRLs recommended by JECFA for **Apramycin** in cattle and chicken kidneys at step 4 and noted JECFA's inability to recommend MRLs for the other tissues and species due to data limitation.

MRLs for **Apramycin** for cattle and chicken kidneys should be held at step 4 until there is a validated analytical method for conducting depletion studies for other species and tissues.

Darquantel

African Experts accepted the MRLs recommended by JECFA for **Darquantel** for sheep muscle, liver, kidney and fat. However, MRL for sheep milk should be held at step 4 until data is made available.

MRLs for **Darquantel** for sheep muscle, liver, kidney and fat to advance to step 5. MRL for sheep milk should be held at step 4.