European Union comments for the

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS 23rd Session

Agenda Item 6:

Proposed draft MRLs for ivermectin, teflubenzuron and lasalocid sodium (CX/RVDF 16/23/6 and REP15/RVDF - Appendix V)

European Union Competence European Union Vote

Ivermectin

1. Draft MRL for muscle (step 4)

The EU notes that the proposed draft Codex MRL for muscle corresponds to the value adopted at EU level. Therefore, the EU can support the proposed draft MRL.

2. Draft MRLs for ivermectin for fat, kidneys and liver (step3)

Draft Codex MRLs for fat, liver and kidneys are higher than the values adopted at EU level. However, the EU notes that these are acceptable from a consumer safety perspective. Therefore, the EU does not object to the proposed draft MRLs for ivermectin in fat, kidneys and liver.

Teflubenzuron (step 3)

The proposed draft Codex MRLs are lower than the corresponding EU MRLs, hence do not constitute a consumer safety concern. <u>The EU does not object to the proposed draft MRLs for</u> teflubenzuron.

Lasalocid sodium (step 4)

The EU takes note of the opinion of the 81st meeting of JECFA and appreciates the responses given in relation to the concerns expressed by the EU at the 22nd CCRVDF meeting.

In addition, the EU appreciates that JECFA is working on the development of methodologies for the derivation of a microbial acute reference dose (mARfD) as, in the absence of internationally agreed methodology, the concern previously raised by the EU cannot be addressed in a fully satisfactory manner.

In addition, the EU has concerns about the use of the Estimated Daily Intake (EDI) approach to estimate consumer exposure. By using the EDI approach JECFA estimated the consumer intake to represent approximately 27% of the overall (toxicological) ADI. However, when using the Theoretical Maximum Daily Intake (TMDI) approach to estimate consumer exposure, the proposed draft Codex MRLs lead to a consumer intake of 882.11 μ g/person, which represents 294% of the overall (toxicological) ADI and when the EU MRL for eggs is also included, the TDMI amounts to 921.58 μ g, representing approximately 303% of the ADI. Therefore, the EU considers that the proposed draft MRLs may represent a risk to consumers.

In light of the above the EU cannot support the proposed draft Codex MRLs for lasalocid sodium.