15/04/2015

European Union comments for the

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
22nd Session

San José, Costa Rica, 27 April – 1 May 2015

Agenda Item 6c

Proposed draft MRLs for derquantel, emamectin benzoate, ivermectin, lasalocid sodium and monepantel

(CX/RVDF 15/22/6)

European Union Competence
European Union Vote

Derquantel

The proposed draft Codex MRLs for derquantel are lower than the corresponding EU MRLs and consequently do not represent an increased risk to consumer safety. Therefore, the EU will not object to the proposed draft MRLs for derquantel.

Emamectin benzoate

The proposed draft Codex MRLs for emamectin are numerically identical to the corresponding EU MRLs. Therefore, the EU can support the proposed draft MRLs for emamectin.

Ivermectin

The proposed draft Codex MRL for ivermectin in cattle muscle is lower than the corresponding EU MRL and consequently does not represent an increased risk to consumer safety. However, the EU notes that ivermectin is proposed for JECFA re-evalution based on new data. The EU suggests not adopting the proposed draft MRL but retaining them at step 4 pending the JECFA re-evaluation.

Lasalocid sodium

The EU does not support the proposed draft Codex MRLs for lasalocid sodium because a risk to consumer health is identified: a short term exposure to residues may exceed the level identified by JECFA as representing a risk for disruption of the colonisation barrier (microbiological ADI). A concern form with further details has been submitted.

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 µg/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 µg, representing approximately 303% of the ADI. Therefore the EU considers that the proposed draft MRLs may represent a risk to consumers.

Monepantel

The overall ADI established by JECFA for monepantel is lower than the ADI established in the EU, and as such, does not represent a consumer safety concern.

JECFA used the EDI approach to estimate consumer exposure with the result that consumer intake was estimated to represent 37% of the JECFA ADI. However, when using the TMDI approach to estimate consumer exposure, the proposed draft Codex MRLs lead to a consumer intake of 2134 µg/person, which is equivalent to 118% of the EU ADI, and when the EU MRL for milk is also included, the TMDI is 2409 µg/person, which is equivalent to 134% of the EU ADI. Therefore, the EU considers that the proposed draft MRLs may represent a risk to consumers and consequently the EU cannot support the proposed draft Codex MRLs for monepantel.