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Codex Committee on Residues of Veterinary Drugs in Foods
20th Session

San Juan, Puerto Rico, 7-11 May 2012

European Union comments on the
Proposed Draft Maximum Residue Limits for Veterinary Drugs

Agenda item 6, CX/RVDF 12/20/6

European Union competence
European Union vote

Amoxicillin

The proposed draft Codex MRLs are numerically identical to those established in the EU. Therefore, the EU can accept the proposed draft MRLs for amoxicillin in cattle, sheep and pig tissues.

Apramycin

The EU notes that JECFA has not finalised its evaluation of apramycin and has asked for substantial data on different species. In the absence of the necessary data, JECFA is not yet in a position to propose MRLs for tissues except cattle and chicken kidney, in which temporary MRLs are proposed. The EU does not support this approach because:

- full information on metabolism and distribution in all tissues should first be known before MRLs are determined, as the proposed MRLs should reflect tissue distribution.

- establishing MRLs only in kidney does not provide a useful tool for residue control (particularly as kidney is probably not heavily traded internationally)

For the above reasons, the EU cannot support the proposed draft temporary MRLs for apramycin in cattle and chicken kidney. The EU suggests reconsidering the MRLs for apramycin after JECFA has received the requested data and recommended MRLs in all relevant tissues.

Derquantel

For derquantel, the safety assessments of JECFA and the relevant EU scientific body (CVMP[1]) differ with an ADI of 1 µg/kg body weight established in the EU and an ADI of 0-0.3 µg/kg body weight established by JECFA. The lower JECFA ADI is partly explained by the fact that JECFA applied a safety factor of 300 while CVMP applied a safety factor of 100.

The proposed draft Codex MRLs for derquantel are lower than the established EU MRLs and consequently do not represent an increased risk to consumer safety. Therefore, the EU can accept the proposed draft MRLs for derquantel in ovine tissues.

Monensin

The use of monensin in food producing animals for growth promotion purposes is not authorised in the EU. Monensin is authorised in the EU as a veterinary drug in cattle and as a feed additive for the control of coccidiosis in chicken and turkey.

For monensin, the safety assessments of JECFA and the relevant EU scientific bodies (CVMP and EFSA[2]) differ with an ADI established in the EU of 3 µg/kg bw, 180 µg/person, and an ADI established by JECFA of 0–10 µg/kg bw, up to 600 µg/person.

For monensin in cattle, the existing Codex MRLs for muscle, fat and kidney and the proposed draft Codex MRL for liver are higher than the corresponding EU MRLs. They would lead to a maximum intake exceeding the EU ADI by 140 %. For this reason, the EU has safety concerns about the proposed draft Codex MRL for monensin in cattle liver.

Monepantel

The JECFA ADI for monepantel (0-20 µg/kg) is lower than the ADI established in the EU (30 µg/kg), and as such does not represent a consumer safety concern.

The proposed draft Codex MRLs for monepantel are lower than those established in the EU and consequently do not represent a consumer safety concern. Therefore, the EU can accept the proposed draft MRLs for monepantel in ovine tissues.

Narasin

The draft Codex MRLs for narasin in cattle tissues do not raise concerns purely from consumer safety point of view[3]. Nevertheless, the EU continues to have concerns about the draft Codex MRLs as narasin is used in cattle primarily for growth promotion. Such use is not authorised in the EU because of the general EU policy of not allowing the use of veterinary drugs for non-therapeutical purposes.

[1] Committee for Medicinal Products for Veterinary Use, European Medicines Agency
[2] European Food Safety Authority,
[3] Scientific report of EFSA to the European Commission to assess the draft Codex MRLs for narasin in pig and cattle, EFSA Journal 2012;10(1):2547