30/11/2020

Reply of the European Union to CL 2020/17-RVDF

on maximum residue limits for veterinary drugs

European Union competence/European Union Vote

Flumethrin

The European Union (EU) supports the draft MRL for flumethrin in honey because it does not raise any consumer safety concern. This draft MRL is more conservative than the EU MRL.

Diflubenzuron

The EU supports the proposed draft MRL for diflubenzuron in salmon because it does not raise any consumer safety concerns. This proposed draft MRL is the same as the EU MRL.

Halquinol

The EU notes that halquinol is an antimicrobial agent, which is indicated for use in pigs and poultry as a growth promoter and for controlling diarrhea. The EU emphasises that the use of antimicrobial agents, including halquinol, is not authorised in the EU for growth promotion and recalls that the use of antimicrobials for growth promotion does not correspond to a prudent use of antimicrobials, which is necessary to fight antimicrobial resistance. The EU therefore wishes to voice its strong concerns as to the establishment of MRLs for halquinol. Halquinol is not authorised as a veterinary medicinal product nor as a feed additive in the EU, therefore no MRLs are established for halquinol in the EU.

Ivermectin

The EU notes that the proposed draft MRLs for ivermectin incorporate a substantial safety margin. For this reason, they are considerably lower than those established in the EU and, while not representing a consumer safety concern, would pose a difficulty in relation to established Good Practice in the use of Veterinary Drugs (GPVD).

In view of the substantial margin of safety, the EU proposes that CCRVDF requests JECFA to review its recommendation with a view to setting MRLs that are compatible with established GPVD. A concern form with further details is attached.

CONCERN FORM

Submitted by: The European Union

Date: 30 November 2020

Veterinary drug: Ivermectin

Commodity (species and tissues): Sheep, pig and goat tissues

MRL (µg/kg):

Species	Fat	Kidney	Liver	Muscle
Sheep, pigs and goats	20 µg/kg	15 µg/kg	15 µg/kg	10 µg/kg

Present Step: Step 3

Description of the concern:

It is an established principle that one of the factors to be considered when setting MRLs is Good Practice in the use of Veterinary Drugs (GPVD), defined in the Codex Alimentarius Commission Procedural Manual as "the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions".

JECFA calculated chronic dietary exposure based on estimated residues in cattle, sheep and pigs to be below 6% of the ADI (the reported Global Estimate of Chronic Dietary Esposure values for the general population and for children are 4% and 5.9% of the upper bound of the ADI, respectively). The available data did not allow JECFA to estimate acute dietary exposure on the basis of residues in pigs or goats but, based on data relating to residues in injection site muscle in sheep, acute dietary exposure was estimated to be below 1% of the ARfD (the reported Global Estimate of Acute Dietary Exposure is 0.6% and 0.5% for adults and children, respectively).

From the above, it is clear that the recommended MRLs incorporate a substantial safety margin relative to the ADI and ARfD.

The recommended MRLs are considerably lower than those established in the EU and would pose a difficulty in relation to established GPVD. Indeed, TRS 1023 indicates that for sheep and pigs the recommended MRLs relate to withdrawal periods of 65 and 35 days, respectively. This is considerably longer than established withdrawal periods for many ivermectin-containing products for sheep and pigs authorised in the EU.

In view of the substantial margin of safety between the estimated dietary exposure estimate and the ADI and ARfD, it would seem appropriate to request JECFA to review its recommendation with a view to setting MRLs that are compatible with established GPVD.

Summary of the supporting documentation that will be submitted to JECFA (e.g. toxicology, residue, microbiology, dietary exposure assessment):

Examples of product information for authorised products.