30 April 2009

Codex Committee on Residues of Veterinary Drugs in Foods (18th Session) Natal, Brazil, 11-15 May 2009

European Community comments on the Proposed Draft Maximum Residue Limits for Veterinary Drugs (avilamycin, dexamethasone, monensin, narasin, tilmicosin, triclabendazole, tylosin)

Agenda item 5 (b), CX/RVDF 09/18/5

European Community competence
European Community vote

The European Community (EC) would like to thank JECFA for the comprehensive report of the 70 JECFA meeting. At the same time, the EC regrets that the full report came available only at the very late stage which made it very difficult to prepare for the 18th CCRVDF session. In the future, the schedule of the JECFA meetings and the CCRVDF sessions should be arranged in a way that would allow the availability of the full JECFA reports well in advance of the CCRVDF sessions.

As for the proposed draft MRLs, the EC wishes to make the following comments:

Avilamycin:

For avilamycin the proposed draft Codex MRLs are equivalent or greater than the current EC MRLs. However, the theoretical maximum daily intake (TMDI) calculated using the proposed draft Codex MRLs remains below the Admissible Daily Intake (ADI) established by the EC (TMDI = 63.3% of the EC ADI). Therefore, from a consumer safety perspective the EC can accept the proposed draft Codex MRLs for avilamycin.

Dexamethasone:

For dexamethasone the EC ADI and the ADI established by JECFA are the same, with (0-0.015) µg/kg bw/day = (up to) 0.9 µg/person. The proposed draft Codex MRLs for dexamethasone are equivalent or greater than the current EC MRLs.

The TMDI calculated using the proposed draft Codex MRLs exceeds the ADI (TMDI = 111% of the ADI). However, taking into account that dexamethasone is rapidly eliminated from muscle and milk the EC can accept the proposed draft Codex MRLs for dexamethasone from a consumer safety perspective.

Monensin:

The use of monensin in food producing animals for growth promotion purposes is not authorised in the EC. Monensin is authorised in the EC 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 EC scientific bodies (CVMP and EFSA/FEEDAP) differ with an ADI established in the EC 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. Effects considered relevant by the EC bodies were apparently disregarded by the JECFA in its evaluation.

For monensin in cattle, the proposed draft proposed Codex MRLs differ from the current EC MRLs (with some proposed draft Codex MRLs being higher and some lower than the EC MRLs). However, the TMDI calculated using the proposed draft Codex MRLs remains below the EC ADI (TMDI = 89% of the EU ADI). Therefore, from a consumer safety perspective the EC can accept the proposed draft Codex MRLs for monensin in cattle.

For monensin in poultry, the proposed draft Codex MRLs are all higher than the current EC MRLs. However, the TMDI calculated using the proposed draft Codex MRLs leads only to a negligible excess of the EC ADI (TMDI = 102% of the EU ADI). Therefore, from a consumer safety perspective, the EC can accept the proposed draft Codex MRLs for monensin in poultry.

For monensin in sheep and goats, the EC position on the proposed draft Codex MRLs will be established once the JECFA safety evaluations have been reviewed. This review could not yet be completed as the full JECFA report only came available on 20 April.

Narasin:

The use of narasin in food producing animals for growth promotion purposes is not authorised in the EC. Narasin is authorised in the EC as a feed additive for the control of coccidiosis in chicken.

For narasin in chicken, the EC ADI and the ADI established by JECFA are the same with 5 µg/kg bw/day. For liver and fat, the proposed draft Codex MRLs are the same as the current EC MRLs. Therefore, the EC can accept the proposed draft Codex MRLs for narasin in chicken liver and fat. The current EC MRLs for kidney and muscle are higher than the proposed draft Codex MRLs. The EC position on the proposed draft Codex MRLs for narasin in chicken will be established once the availability of analytical methods with sufficient sensitivity for residues in kidney and muscle has been verified.

For narasin in cattle and pigs, the EC position on the proposed draft Codex MRLs will be established once the JECFA safety evaluations have been reviewed. This review could not yet be completed as the full JECFA report only came available on 20 April.

Tilmicosin:

At the 11th CCRVDF meeting (1998) the EC did not support the proposed Codex MRLs and proposed a re-consideration of the evaluation with regard to the ADI. The JECFA ADI is derived from a 12-month toxicity study in dogs while the EC established a microbiological ADI based on an in vivo study with human flora associated (HFA) rats. The EC remains of the view that the microbiological potential of tilmicosin needs to be taken into account, and considers that an ADI of 40 mg/kg bw per day, as proposed by JECFA, is not acceptable because of a potential microbiological risk to the consumer.

As the TMDI calculated using the proposed draft Codex MRLs for chicken and turkey tissues and the EC MRL for milk significantly exceed the EC ADI (TMDI = 313% of the EC ADI) the EC considers that the proposed MRLs may represent a risk to consumers. Therefore, the EC cannot support the proposed draft Codex MRLs for tilmicosin.

The EC notes that JECFA estimated consumer exposure using the EDI approach. While the EC has indicated that it accepts that the EDI represents a more realistic estimate of chronic exposure to residues than the TMDI, the EC has a number of reservations over the use of the EDI approach, most notably that occasional high exposures that may result in acute toxicity need to be considered separately. For tilmicosin this is particularly relevant as the EC ADI is based on effects on the colonisation barrier, and the possibility of such effects arising as a result of short term exposures has not been ruled out.

Triclabendazole:

For triclabendazole the proposed draft Codex MRLs differ from the current EC MRLs (with some proposed draft Codex MRLs being higher and some lower than the EC MRLs).

The TMDI calculated using the proposed draft Codex MRLs exceeds the EC ADI (TMDI = 124% of the ADI). However, taking into account that triclabendazole is considered to have low acute toxicity the EC can accept the proposed draft Codex MRLs for triclabendazole from a consumer safety perspective.

Tylosin:

For tylosin the ADI established by JECFA is 5 times higher than the ADI established by the EC.

The EC can accept the proposed draft Codex MRLs in cattle, pig and chicken tissues as they are the same as those established in the EC. The proposed draft Codex MRLs for milk and eggs are higher than the current EC MRLs. The TMDI calculated using the proposed draft Codex MRLs exceeds the EC ADI (TMDI = 117% of the ADI). The acceptability of the JECFA MRLs milk and eggs hinges on whether or not the ADI established by JECFA at its 70th meeting (which is 5 x the EC ADI) can be accepted. Unfortunately it was not yet possible to evaluate whether the JECFA ADI is acceptable as the full JECFA report including the assessment of the toxicological data only came available on 20 April. The final EC position on the proposed draft Codex MRLs for tylosin in milk and eggs will be established as soon as the evaluation of the JECFA ADI is accomplished.