European Medicines Agency
Veterinary Medicines and Inspections

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NOTE REGARDING THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS FOR MORANTEL

An application for the establishment of maximum residue limits for morantel was submitted to the European Commission in 1992 under Article 7 of Council Regulation (EEC) No 2377/90, as a so-called "old substance". The Committee for Veterinary Medicinal Products (CVMP) with the support of its Safety of Residues Working Party assessed the data in November 1998, recommended the establishment of provisional Maximum Residue Limits and agreed a list of questions to be addressed by the applicant. In October 2000, the CVMP further recommended a 2-year extension of the provisional Maximum Residue Limits in order to allow for the completion of scientific studies in progress.

Further to the assessment of the responses submitted and consideration of an appeal from the applicant on the negative opinion adopted by the CVMP in December 2003, the Committee recommended the inclusion of morantel in Annex II of Council Regulation (EC) No 2377/90 for bovine and ovine species, in June 2003.

In November 2003 the European Commission requested the CVMP to reconsider the assessment of morantel taking into account the importance of having MRL values established to set adequate withdrawal periods in cases where the residues of morantel in foodstuffs from treated animals, may supersede the acceptable daily intake 24 hours after administration of slow release veterinary medicinal products.

The CVMP reconsidered its opinion on morantel and confirmed at its meeting in February 2004 that an establishment of MRLs for morantel was not deemed necessary for the protection of public health in view of the rapid depletion of residues of morantel.

The Commission taking into account the need to establish adequate withdrawal periods to provide safeguards for the consumer and to allow relevant controls of morantel in foodstuffs of treated animals, decided not to follow the CVMP opinion and subsequently adopted Commission Regulation (EC) No 1851/2004[1] including morantel in Annex I of Council Regulation (EEC) No 2377/90 as follows:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Morantel	Sum of residues which may be hydrolysed to N-methyl-1,3-propanediamine and expressed as morantel equivalents	Bovine, ovine	100 µg/kg 100 µg/kg 800 µg/kg 200 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk	

Article 12 of Council Regulation (EEC) No 2377/90 requires that, after amendments to the annexes of the Regulation, the summary of the assessment of the substance by the CVMP is published. The summary report on morantel, currently published on the EMEA web site, is the summary of the assessment carried out by the CVMP, which recommended inclusion of morantel in Annex II of Council Regulation (EEC) No 2377/90 for bovine and ovine species. For the reasons given above, MRLs adopted by the European Commission are not consistent with the recommendation of the CVMP.

Morantel summary report

[1] OJ L 323 of 26.10.2004, p.6 http://pharmacos.eudra.org/F2/register/regpdf/2004_10_25-1851.pdf

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