



## COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

### TRIMETHOPRIM

(Extension to all food producing species)

### SUMMARY REPORT (3)

1. Trimethoprim is a diaminopyrimidine antimicrobial agent which is currently entered into Annex I of Council Regulation (EEC) No. 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Trimethoprim	Trimethoprim	Bovine	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk	
		Porcine	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Skin + fat Liver Kidney	
		Poultry	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Skin + fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
		<i>Equidae</i>	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg	Muscle Fat Liver Kidney	
		Fin fish	50 µg/kg	Muscle and skin in natural proportions	

2. Following concern that an insufficient number of medicinal products was available to treat diseases occurring in animals, and especially diseases occurring in minor animal species, the CVMP conducted a review of the risk assessment approach for the establishment of MRLs and adopted a Note for Guidance on Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin (EMA/CVMP/187/00-FINAL). The Note for Guidance allows for an extrapolation of MRLs to all food producing species, where identical or slightly different MRLs (i.e. MRL values normally in the same order of magnitude) have been set in cattle (or sheep), pigs and chicken (or poultry).

3. The MRLs already established for trimethoprim fulfil the above criteria. The existing MRLs for tissues are identical for all species except Equidae. Therefore it would be possible to extend the MRLs so that the same values would apply to all food producing species except Equidae.
4. An analytical method for monitoring residues of trimethoprim in the edible tissues of bovine, porcine, poultry, Equidae and fin fish and in bovine milk was available. An assessment of the applicability of this method indicated that extrapolation to the tissues and milk of other species should not be problematic.

### Conclusions and recommendation

Having considered that:

- a microbiological ADI of 252 µg/person was previously established for trimethoprim,
- MRLs have previously been established in bovine, porcine, poultry, Equidae and in fin fish; except for Equidae, the MRLs for these species are identical,
- an analytical method for the monitoring of residues in tissues and milk was available;

the Committee for Veterinary Medicinal Products recommends the inclusion of trimethoprim in Annex I of Council Regulation (EEC) No. 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Trimethoprim	Trimethoprim	All food producing species except <i>Equidae</i>	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle* Fat** Liver Kidney Milk	Not for use in animals from which eggs are produced for human consumption
		<i>Equidae</i>	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg	Muscle Fat Liver Kidney	

\*For fin fish this MRL relates to “muscle and skin in natural proportions”

\*\*For porcine and poultry species this MRL relates to “skin and fat in natural proportions”

It was estimated that extending the MRLs to all food producing species, as proposed above, would result in a consumer intake not exceeding 46% of the ADI.