

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

TYLOSIN

(Extension to all food producing species)

SUMMARY REPORT (5)

1. Tylosin is a macrolide antibiotic 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
Tylosin	Tylosin A	Bovine	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			100 µg/kg	Liver	
			100 µg/kg	Kidney	
			50 µg/kg	Milk	
		Porcine	100 µg/kg	Muscle	
			100 µg/kg	Skin + fat	
			100 µg/kg	Liver	
			100 µg/kg	Kidney	
		Poultry	100 µg/kg	Muscle	
			100 µg/kg	Skin +fat	
			100 µg/kg	Liver	
			100 µg/kg	Kidney	
			200 µg/kg	Eggs	

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 tylosin fulfil the above criteria. The existing MRLs are identical and so it would be possible to recommend extension of the MRLs in such a way that the same MRLs values would apply to all food producing species.
4. An analytical method for monitoring residues of tylosin in the edible tissues of bovine, porcine and poultry and in eggs 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 360 µg/person was previously established for tylosin,
- MRLs have previously been established in bovine and porcine species and in poultry; these MRLs are identical,
- an analytical method for the monitoring of residues in tissues, eggs and milk was available;

the Committee for Veterinary Medicinal Products recommends the inclusion of tylosin 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
Tylosin	Tylosin A	All food producing species	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg 50 µg/kg 200 µg/kg	Muscle* Fat ** Liver Kidney Milk Eggs	

* 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 80% of the ADI.