



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

SPECTINOMYCIN

(Extension to all food producing species)

SUMMARY REPORT (5)

1. Spectinomycin is an aminocyclitol 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
Spectinomycin	Spectinomycin	Bovine	300 µg/kg 500 µg/kg 1000 µg/kg 5000 µg/kg 200 µg/kg	Muscle Fat Liver Kidney Milk	
		Porcine, chicken	300 µg/kg 500 µg/kg 1000 µg/kg 5000 µg/kg	Muscle Skin +fat Liver Kidney	

2. Spectinomycin is also currently entered into Annex III 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
Spectinomycin	Spectinomycin	Ovine	300 µg/kg 500 µg/kg 2000 µg/kg 5000 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.1.2002. Not for use in animals from which milk is produced for human consumption.
		Chicken	200 µg/kg	Eggs	Provisional MRLs expire on 1.1.2002.

Final MRLs were recently recommended for ovine species. The proposed final MRLs would have the same values as the current provisional MRLs with the addition of an MRL of 200 µg/kg for ovine milk. No final MRLs were recommended for chicken eggs.

3. 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 (EMEA/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).
4. The MRLs already established for spectinomycin fulfil the above criteria. Except for the higher MRL value for ovine liver, the existing MRLs are identical. Therefore it was considered appropriate to recommend extension of the MRLs in such a way that the same MRLs values would apply to all food producing species, except for ovine species, for which the current MRL values would be retained.
5. An analytical method for monitoring residues of spectinomycin in the edible tissues of bovine, ovine and porcine species and chickens and in bovine and ovine 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 2400 µg/person was previously established for spectinomycin,
- MRLs have previously been established in bovine, ovine and porcine species and in chickens; except for a higher MRL value for ovine liver, these MRLs are identical,
- an analytical method for the monitoring of residues in edible tissues and milk was available;

the Committee for Veterinary Medicinal Products recommends the inclusion of spectinomycin 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
Spectinomycin	Spectinomycin	All food producing species except ovine	300 µg/kg 500 µg/kg 1000 µg/kg 5000 µg/kg 200 µg/kg	Muscle* Fat ** Liver Kidney Milk	Not for use in animals from which eggs are produced for human consumption
		Ovine	300 µg/kg 500 µg/kg 2000 µg/kg 5000 µg/kg 200 µg/kg	Muscle Fat Liver Kidney Milk	

* 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 70% of the ADI.