



## COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

### EMAMECTIN (Extension to fin fish)

#### SUMMARY REPORT (2)

1. Emamectin is an avermectin that is structurally very similar to eprinomectin the only difference being the presence of an epi-methylamino group at the C4' position in the emamectin molecule rather than an epi-acetylamino group at that position in the case of eprinomectin. The benzoate salt was developed for the treatment of sealice infestations in *Salmonidae*. Emamectin 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
Emamectin	Emamectin B1a	<i>Salmonidae</i>	100 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 (EMEA/CVMP/187/00-FINAL). This Note for Guidance and the Note for Guidance on the establishment of maximum residue limits for minor animal species (EMEA/CVMP/153a/97/97-FINAL) allows for an extrapolation of MRLs to the corresponding minor animal species.
3. The MRL already established for emamectin fulfil the above criteria and therefore it was considered appropriate to recommend the modification of the entry in Annex I for *Salmonidae* in such a way that the same MRL value would apply to fin fish.
4. An analytical method for monitoring residues of emamectin in Atlantic salmon was available. An assessment of the applicability of this method indicated that it is appropriate also in other fin fish species.

## Conclusions and recommendation

Having considered that:

- an ADI of 1 µg/kg bw (i.e. 60 µg/person) was established for emamectin base,
- an MRL has previously been established for *Salmonidae*,
- emamectin B1a was identified as the marker residue in fish muscle and skin and comprised approximately 90% of the total residues during the period 12 hours to 30 days after treatment, the amount depending on water temperature,
- a validated analytical method for the determination of residues of emamectin B1a is available;

the Committee for Veterinary Medicinal Products recommends the inclusion of emamectin 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
Emamectin	Emamectin B1a	Fin fish	100 µg/kg	Muscle and skin in natural proportions	

Based on this MRL, the daily intake of total residues will represent approximately 62% of the ADI.