



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

SULPHUR

(Extension to all food producing species)

SUMMARY REPORT (2)

1. Sulphur (CAS 7704-34-9) has been used in human and veterinary medicine for many years as a keratolytic, mild antiseptic, antifungal and parasiticide. It is also used in homoeopathic medicine. Sulphur is currently entered into Annex II of Council Regulation (EEC) No. 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Sulphur	Bovine, ovine, caprine, <i>Equidae</i> , porcine	

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). This Note for Guidance and also the Note for Guidance on the Establishment of Maximum Residue Limits for Minor Animal Species (EMA/CVMP/153a/97-FINAL) state that the existing Annex II entry for a major species should normally also refer to the corresponding minor species. The criteria for extension of Annex II entries to all food producing species were originally laid down in the Working Document: Criteria for inclusion of substances into Annex II of Council Regulation (EEC) No. 2377/90 and extension of Annex II classification to other species (III/5935*/94-EN). The Note for Guidance on Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin (EMA/CVMP/187/00-FINAL) reiterated these criteria.
3. A request was submitted to the EMA, whether it would be possible to extend the existing entry in Annex II of Council Regulation (EEC) No. 2377/90 to all food producing species, in accordance with the above guidelines.
4. Sulphur is widely distributed in nature and is naturally present in many foods and is an essential nutrient in the diet of ruminants. The substance fulfills the criteria laid down for the extension of the Annex II entry to all food producing species.

Conclusions and recommendation

Having considered that:

- sulphur is a normal component of the diet of humans and animals,
- sulphur has already been included in Annex II of Council Regulation (EEC) No. 2377/90, as amended, for bovine, ovine, caprine, *Equidae* and porcine species;

the Committee for Veterinary Medicinal Products recommends the inclusion of sulphur in Annex II of Council Regulation (EEC) No. 2377/90, as amended, in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Sulphur	All food producing species	