



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

**NOTE FOR GUIDANCE ON THE ESTABLISHMENT OF MAXIMUM RESIDUE
LIMITS FOR *SALMONIDAE* AND OTHER FIN FISH**

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NOTE FOR GUIDANCE ON THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS FOR *SALMONIDAE* AND OTHER FIN FISH

In accordance with the CVMP guideline on the establishment of MRLs for minor species of food producing animals (EMA/CVMP/153a/97-FINAL), *salmonidae* are currently considered as a major species.

Recognising that MRLs have been established for only a very few substances used as active ingredients in medicinal products for fish, the CVMP has considered it appropriate to review the technical data requirements for setting MRLs for products used in *salmonidae* and other fin fish.

Taking into account, that:

- to date, for substances that have been evaluated, the marker residue determined for any given substance used in *salmonidae* has been identical to that established in other animal species;
- the target tissue considered appropriate for *salmonidae* is muscle, including skin in natural proportions, and that in *salmonidae* muscle is not a tissue where significant metabolism occurs;
- even though available data comparing the metabolism of veterinary drugs in *salmonidae* and other animal species are rather scarce, significant differences between the metabolic profile of substances used in fish and other species are not apparent;
- the only difference in metabolism of medicines in fish and other species appears to be the rate at which it occurs, with metabolism in fish being slower than in mammals, particularly when the temperature of the water of their environment is low;

a pragmatic approach, as adopted in deriving revised guidelines for minor species, should also apply to the establishment of MRLs for substances used in *salmonidae* and other fin fish:

- An extrapolation can be considered acceptable, whereby if an MRL has been established for a substance in muscle in a major mammalian species it may be applied to *salmonidae* and other fin fish as well;
- the parent compound is normally acceptable as a valid marker residue in *salmonidae* and other fin fish.