



SCOTTISH ENVIRONMENT PROTECTION AGENCY

POLICY NO 17

**SEA LICE TREATMENT CHEMICALS
FOR CAGE FISH FARMS :
PROVISIONAL ENVIRONMENTAL QUALITY STANDARDS
FOR AZAMETHIPHOS**

**Version 2
November, 1998**



1. Background

- 1.1 At their meeting of 11th March 1997 the SEPA Board considered a report prepared by their Fish Farming Advisory Group : *Risk Assessment of Azamethiphos - A review of ecotoxicity and current policy*. The Board accepted the report and endorsed the recommendations that it contained regarding provisional environmental quality standards for azamethiphos, as used for the control of sea lice infestation of caged salmon. They also accepted that it might be appropriate to review the standards proposed in that assessment, in the light of new information and experience. Authority to make such changes was given to SEPA's Fish Farming Advisory Group.
- 1.2 Novartis Animal Health UK Ltd are manufacturers of the commercial product 'Salmosan', the active ingredient of which is azamethiphos. In response to SEPA's risk assessment, Novartis commissioned a report by Dr John McHenery of Inveresk Research, Tranent, Scotland. His report - '*Comments on SEPA's Risk Assessment of Azamethiphos*' (R257/A/01) was submitted to Novartis in September 1997 and subsequently made available to SEPA.
- 1.3 McHenery conducted much of the experimental studies of the toxicity of azamethiphos upon which assessments have been based. He was therefore able to provide detailed results not previously made available. These data and his accompanying discussion persuaded the FFAG that more relaxed environmental quality standards were justified.

2. Current standards

- 2.1 In the absence of data on short term toxic effects SEPA's original 3 hour standard was derived from the 96 hour No Observable Effect Concentration (NOEC) for acetyl cholinesterase (AChE) inhibition in lobster larvae: 160 ng/l. McHenery provided data for 5 hour NOEC which, with the application of a x10 factor gives a **maximum allowable concentration (MAC) after 3 hours of 250 ng/l**. This was accepted by the FFAG (15/12/97) to be a more appropriate derivation.
- 2.2 A 1994 assessment of azamethiphos for the Association of Directors and River Inspectors for Scotland (ADRS) suggested that an appropriate 24 hour Likely Safe Environmental Concentration would be 80 ng/l. This figure was derived from the 552 hour NOEC for AChE inhibition for lobster larvae. Although there was no perceived requirement for a 24 hour standard for the proposed regulatory strategy, SEPA agreed to retain this. McHenery in his report to Novartis suggested that the derivation of a 24 hour standard used by the Veterinary Medicines Directorate was more appropriate : the 96 hour EC50 for lobster larvae with an extrapolation factor of 10. The FFAG agreed to adopt this, giving a **24h MAC of 150 ng/l**.
- 2.3 The SEPA assessment proposed that an appropriate predicted no effect concentration (PNEC) would be 5 ng/l, based upon application of a 100 fold factor to the 96 hour LC50 to lobster larvae. This was accepted as a suitable standard for

chronic effects and adopted for use at 72 hours. Data provided by McHenry suggested a 70 h EC50 of 410 ng/l. Application of a 10 fold factor to this gives a **72h MAC of 40 ng/l**. This was accepted by the FFAG at their 15/12/98 meeting.

- 2.4 The above MACs were considered by staff of the Water Research Centre, Medmenham, in a peer review for SEPA in April 1998. The WRc concluded that data from an appropriate organism (lobster) and suitable exposure periods had been used. Suitable end points and extrapolation factors were considered to have been used for the 24h and 72h standard, but reservations were expressed regarding the 3 hour standard. It was suggested that effects data such as acute toxicity, if available, would have been more appropriate than NOEC based upon lethargy/moribund behaviour. Related to this was the observation that application of a 10 fold extrapolation factor to the NOEC may be over precautionary. Notwithstanding these reservations on the part of WRc, the FFAG drew comfort from their conclusions and resolved to apply the MACs highlighted above (FFAG:20/4/98).

3. Application of standards

- 3.1 In parallel with the development of provisional environmental quality standards, the FFAG have considered appropriate protocols by which the standards should be applied in the regulation of caged fish farms. These aspects of SEPA's involvement are referred to in SEPA's 1998 Manual of Procedures for the Regulation and Monitoring of Cage Fish Farms, particularly those sections concerning the setting of consent limits and the use of models.