



Attachment XIV

Guidance note on the licensing of discharges of AMX (deltamethrin) at marine cage fish farms

**Version 1.0
6 June 2008**

Key Points

This document provides guidance for SEPA staff on the new sea lice medicine AMX based upon the active ingredient deltamethrin

It should be useful to all staff dealing with CAR activities such as licensing, monitoring and inspections.

Introduction

Salmon grown in marine cage fish farms may from time to time become infested with parasitic sea lice. Sea lice are small crustaceans and those affecting salmon in Scottish waters are two species *Lepeophtheirus salmonis* and *Caligus elongatus*. The lice attach to the salmon piercing the skin of the fish to feed on blood. Heavy infestations can pose a risk to the welfare of the fish both due to the direct effect of the lice and through making the fish more susceptible to secondary infections. Heavy louse burdens on farmed salmon can also pose a risk to wild fish populations because they may lead the release of significant numbers of larvae which may infest wild salmon and sea trout stocks.

Medicines to treat sea lice infestations are administered in two different ways, topically or systemically. Applying medicines topically, a method known as a bath treatment, involves enclosing the fish cage in a tarpaulin and adding to the water in which the fish swim. Systemic or in-feed administration involves giving the medicine to the fish in their diet. The new product will be administered as a bath treatment by enclosing the fish cage and adding to the enclosed water.

SEPA has issued licences under the Water Environment (Controlled Activities) (Scotland) Regulations 2005 (CAR) which permit the release of residues of various sea lice medicines, these are set out in Table 1 below. For various reasons including the restrictions on use imposed by SEPA and commercial decisions by the companies involved, only Slice and Excis have been generally available as sea lice treatments in recent years.

Table 1 Sea lice medicines currently available in the UK

	Name of medicinal product	Active ingredient
Topical (bath) treatments	Salartect (and others)	Hydrogen peroxide
	Excis	Cypermethrin
	Salmosan	Azamethiphos
Systemic (in-feed) treatments	Slice	Emamectin benzoate
	Calicide	Teflubenzuron

Pesticide science suggests that where a target organism is exposed repetitively to the same active ingredient resistance may develop to that ingredient. The current scenario in Scotland, where a small number of active ingredients is available may be likely to promote the development of resistance in sea lice to these products. The availability of a wider range of active ingredients will increase the longevity of all of the available medicines.

The Norwegian pharmaceutical company Pharmaq AS about to market a new sea lice product known as AMX based on the active ingredient deltamethrin in the Scottish and wider European aquaculture markets. The product contains deltamethrin at a concentration of 10mg/ml (10g/l) and is used as a bath treatment applied topically to salmon in cages following enclosure of the cage nets using an impervious tarpaulin. The product has been marketed as a medicine known as "Alphamax" in Norway for a number of years and is fully authorised there. Before it is used on any site, fish farm operators must seek authorisation under the Water Environment (Controlled Activities) (Scotland) Regulations 2005 (CAR) to permit the discharge of the product at marine cage fish farms in Scotland.

SEPA has discussed the product with Pharmaq AS on a number of occasions, setting out the requirements for generic ecotoxicological data and the process of authorising the product on a site-by-site basis at fish farms in Scotland. The issue has been discussed by SEPA management and a proposed methodology has been identified. This methodology has been the subject of a public consultation process which ended on the 19th May 2008.

Mode of action

Deltamethrin is a potent biocide, which formulated as AMX is designed to kill small crustaceans in the form of sea lice. It is a synthetic pyrethroid, closely related to cypermethrin which is already widely used in Scotland and other countries as a sea lice treatment in the product "Excis". Excis is currently licensed by SEPA at approximately 350 cage fish farm sites. Like cypermethrin, deltamethrin is a neurotoxin which acts by interfering with the sodium and potassium channels in the peripheral and central nervous systems of arthropods (a group of animals including insects and crustaceans). Deltamethrin exposure causes repetitive firings of the nerve endings as well as increased and sustained membrane action potentials that overwhelm the muscular neurotransmitters resulting in paralysis and death. AMX is administered topically by enclosing the fish farm cage within an impervious tarpaulin for the duration of the treatment. The treatment concentration is 0.2ml of AMX per cubic metre of enclosed seawater, an equivalent concentration of 2µg/l of deltamethrin.

Environmental Standards

Following a number of meetings with SEPA staff, Pharmaq AS engaged a consultant, Watts and Crane Associates (WCA) to develop a range of standards for deltamethrin. WCA considered a comprehensive range of data including publicly available information and ecotoxicological data derived from studies sponsored by Pharmaq AS and developed the following EQS in Table 2 below.

Table 2: proposed EQS values for deltamethrin

Receiving medium/exposure scenario	Proposed PNEC (ng l-1)	
General water column monitoring to protect against long-term exposure to deltamethrin	0.3 as an Annual Average	
	Period after release (hrs)	(ng l-1)
Water column monitoring after release of deltamethrin from aquaculture facilities	3	9.0
	6	6.0
	12	4.0
	24	2.0
	48	1.0
Sediments	330 ng kg-1 (dry weight)	
Secondary poisoning	2.67 mg kg-1 prey (wet wt)	

The above standards were peer reviewed and subsequently assessed by SEPA staff. SEPA has concluded that the above values have been derived in a robust fashion and are suitable for use as regulatory standards. It is intended that these standards will be integrated into existing methodologies used by SEPA to determine licence applications for the use of sea lice medicines

at marine cage fish farms. Regulatory guidance will also be produced to assist SEPA staff in assessing applications.

Licensing Issues

The existing licensed pyrethroid treatment, Excis, is licensed by SEPA with environmental protection being ensured by numeric limits on the rate of discharge of the medicine derived using a dispersion model. In essence, SEPA seeks to limit the amount of medicine that can be released over a given period to ensure the concentration outwith the vicinity of the farm does not increase to a level that poses a threat to the environment.

The model used in the licensing process simulates the dispersion and dilution of the product over a six hour period following treatment of the fish at a concentration of 5.0µg/l. The amount of product that can be discharged from the cages is limited to that which ensures that the safe environmental standard of 16ng/l for cypermethrin is met as an average within the effluent plume arising from the cages after six hours have elapsed. The model is driven by observed current data, collected at the fish farm site and outputs are site specific. Conditions setting strict limits on the quantities of medicine that may be used over certain time periods are derived from model simulations and set out in the CAR licences for individual fish farms.

For the purposes of modelling, it is accepted that deltamethrin behaves in a similar fashion to cypermethrin. It is therefore appropriate to simulate its release from the cages and subsequent dispersal and dilution and derive relevant licence conditions using a similar modelling approach.

It is intended that modelling of the dispersion of deltamethrin will be undertaken using the six hour approach adopted for cypermethrin; to this end, SEPA is content that the six hour standard of 6ng/l set out above is a suitable standard to be applied in modelling assessments. The similarity between the products and the dilution required to meet the safe environmental concentration from treatment concentration suggests that licence limits for the use of cypermethrin can be relatively simply adapted to limit values for the new product containing deltamethrin, negating the requirement for applicant to undertake additional modelling work.

Thus, where a CAR licence includes conditions limiting the use of Excis, the values set out in such conditions will be multiplied by 0.375 to determine appropriate licence conditions for the new product.

In cases where an application is made to include the new product in a licence which does not already include conditions relating to Excis or in a licence for a new site then the applicant will be required to undertake modelling work to support the application. The modelling requirements utilise the existing model for Excis. Details of the existing model are set out in documentation available on the SEPA website at:

http://www.sepa.org.uk/pdf/guidance/fish_farm_manual/annex/G.pdf

The addition of the new product to an existing licence issued under The Water Environment (Controlled Activities) (Scotland) Regulations 2005 (CAR) will require operators to seek a variation of the fish farm licence. The addition of AMX to a CAR licence for a marine cage fish farm requires the imposition of site specific conditions and is a change to the licence which potentially increases environmental risk through allowing the use and discharge of a biocide. The Regulatory Method WAT-RM-09 defines the circumstances where a variation should be treated as a technical variation as: *“.....An application for a technical variation applies to any*

change to a licence which increases the risk to the environment.” Applications to include AMX in marine cage fish farms are therefore technical variations. Applications for technical variations require to be accompanied a fee of 75% of the full application fee (ie 75% of £2550 or £1912.50).

The chemical structure, toxicity and mode of action of the new product and Excis are very similar. SEPA proposes that in cases where the use and discharge of Excis are permitted by conditions in a fish farm licence that following submission of an application for a technical variation of such a licence, determination will proceed without the requirement for advertisement of the application as set out in Regulation 13 of CAR. Consultation will be undertaken with relevant parties as required.

Where an application is made to include the new product in a licence which does not already include conditions relating to Excis, or in a licence for a new site, then the application will be advertised as set out in Regulation 13 of CAR. Consultation will be undertaken with relevant parties as required.

Details of the practical methodology for dealing with applications for technical variations to add AMX to marine cage fish farm licences are included in Supplement 1 of this Attachment.

The Food and Environmental Protection Act 1985

As discussed above, the medicine may only be used within fish cages and discharged at sites appropriately licensed under CAR. There is the possibility, however, that farmers may seek to discharge the product from wellboats in the vicinity of cage sites. Regulation 4(2) of CAR states that the provisions of CAR “...do not apply to any activity for which a licence is needed under Part II of the Food and Environment Protection Act 1985.” Discharges from vessels in marine waters are generally likely to be an issue requiring a licence under Part II of the Food and Environment Protection Act 1985 (FEPA) and therefore are not regulated under CAR. FEPA is a matter for the Fisheries Research Service (FRS) based at the Marine Laboratory in Aberdeen.

SEPA is consulted by the FRS in relation to any such proposals under FEPA and it is intended that SEPA's stance in connection with such proposals will reflect the position set out in this paper, i.e. that the environmental standards adopted by the Agency should be used in any modelling and licence determination under that Act.

Inspection and monitoring

Detailed guidance on the inspection of marine cage fish farms is set out in Attachment IV of the marine cage fish farm manual. Examining the correct use of sea lice treatment chemicals is an important component of the process of inspecting a farm as inappropriate use of treatments may pose a significant threat to the environment.

There are a number of alternative medicinal products formulated for the treatment of terrestrial animals which are inappropriate for the treatment of salmon, guidance is available on the SEPA website regarding such products.

<http://www.sepa.org.uk/pdf/aquaculture/policies/Deltamethrin.Interim.070817.final.pdf>

Licence conditions associated with AMX will require notification of pending treatments and details of any such treatments undertaken will form part of the data returns which fish farm

operating companies make to SEPA on a quarterly basis. Such notifications provide useful input to the process of inspecting a fish farm allowing completion of a pre-inspection checklist. The data returns for AMX will also form part of the Scottish Pollutant Release Inventory.

SEPA does not require operators to undertake sampling and monitoring of bath treatment residues. Routine audit monitoring by SEPA does however include such parameter. Where deltamethrin residues are detected at sites which do not hold a CAR licence permitting the use and discharge of the substance, further investigatory action including enforcement action if required should be undertaken.

Further guidance

Should further guidance in relation to AMX or deltamethrin be required please contact an Aquaculture Specialist.