



Attachment XIV Supplement 1

Guidance on dealing with technical variations to add AMX (deltamethrin) to licences for marine cage fish farms

**Version 1.0
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1 Background

The sea lice treatment AMX based upon the active ingredient “deltamethrin” was introduced to the market in Scotland during June 2008. Further details of the product, its use and mode of action are set out in Attachment XIV. General details of how to deal with applications made under the water Environment (Controlled Activities) (Scotland) Regulations 2005 (CAR) are set out in the Water Manual and relevant sections of QPulse. Specific guidance on completion of the marine cage fish farm template is available in Attachment I of the fish farm manual available on QPulse. This guidance note seeks solely to discuss approaches to dealing with applications to include AMX in licences for marine cage fish farms. Generic guidance on the processing of CAR applications, the use of CLAS and other similar issues are not covered here but in relevant parts of QPulse and the Water Manual.

2 Variations to include AMX

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.

In order to streamline the process of dealing with applications where the sea lice medicine, Excis based on the active ingredient “cypermethrin” is already authorised, SEPA has determined that such applications should not be advertised. Applications for variations to include AMX at existing sites where Excis is not licensed or at new sites should be advertised in the normal fashion. Consultation with the usual parties should be undertaken for all applications.

3 Dealing with technical variations

Two approaches for dealing with applications for the addition of the medicine are required. These depend upon whether or not the proposal is for a site where the alternative sea lice product Excis is already authorised.

Sites where Excis is already authorised.

The use and discharge of Excis is authorised at approximately 350 marine cage fish farm sites in Scotland. Its use is limited by numeric conditions which define the amount of Excis which can be discharged in any 3 hour period. The limiting condition from the CAR licence template is copied below, and includes an additional sentence referring to it's use in relation to the new product:

The total quantity of cypermethrin, as contained in the trade product Excis, discharged in any consecutive 3 hour period beginning at the time of the first release of Excis as part of any specific treatment, shall not exceed <<X>> grams (this is equivalent to <<X>> millilitres of Excis). Cypermethrin, as contained in the trade product Excis, shall not be discharged if deltamethrin, as contained in the trade product AMX, has been discharged at the premises in the previous 3 hours.

The similarity in chemical structure and mode of action means that the new product AMX can in most cases be authorised at such sites by multiplying the numeric limit on the use of Excis by a factor to derive similar conditions for the product AMX.

SEPA's licensing approach for Excis was relaxed in November 2006 leading to a 2.8 times increase in the quantity of Excis licensed at marine cage fish farm sites in Scotland. This increase in licensed amount was applied to marine cage sites during the CAR transfer and determination process and has been applied to sites subject to applications since this time. A small number of licences have not yet been determined following this change in the policy approach to Excis and for such sites the conditions relating to Excis require to be modified at the same time as the conditions relating to AMX are drafted. This issue is covered in greater detail in a specific guidance note - Reviewed methodology for the use of Excis.

For sites which have been determined under CAR and which have been subject to the 2006 policy approach, the licence values for AMX can be derived from Excis values by multiplying the Excis values by 0.375. Thus where the licence may impose a limit of 100g on the use and discharge of cypermethrin, a limit of 37.5g should be imposed on the use of deltamethrin. The conditions relating to AMX are almost identical to those for Excis, as shown below:

The total quantity of deltamethrin, as contained in the trade product AMX, discharged in any consecutive 3 hour period beginning at the time of the first release of AMX as part of any specific treatment, shall not exceed <<X>> grams (this is equivalent to <<X>> millilitres of AMX). Deltamethrin, as contained in the trade product AMX, shall not be discharged if cypermethrin, as contained in the trade product Excis, has been discharged at the premises in the previous 3 hours.

Similarly to Excis - a 1% solution of cypermethrin, AMX is a 1% solution of deltamethrin. Thus the value for the second part of the condition is derived by multiplying the limit for deltamethrin in grams by 100 to derive a limit for AMX in millilitres.

A requirement of the conditions limiting the use of both Excis and AMX is that simultaneous or near simultaneous use of both products is not permitted. This is because the similarity in chemical structure and mode of action could mean that their effects would be additive were they present in a waterbody at the same time. This would pose an unacceptable risk of impacts upon the environment. Hence the conditions relating to both treatments restrict the use of the treatment where the alternative has been discharged within the previous 3 hours

AMX is a medicine that is used as a bath treatment and thus, in order to ensure environmental protection, in addition to the limits imposed in Condition A1.10 relating directly to AMX, Conditions A1.1, A1.2 and A1.4 should also be imposed. Condition A1.5 may be included in the licence as an alternative to Condition A1.4 depending upon issues such as the proximity of the site to others. Where sites are located in close proximity to each other there may be a risk of simultaneous treatments leading to local exceedence of safe environmental concentrations of AMX. In such cases Condition A1.5 allows SEPA staff to ensure that treatments at neighbouring sites do not occur simultaneously. Condition 1.5 is however normally only applied to discharges of Salmosan but in certain circumstances eg where it has been applied to discharges of Excis, may be applicable to AMX. This issue can also be dealt with in the covering letter WAT-LETT-13 accompanying the licence at the time of issue.

Following derivation of appropriate licence conditions for AMX the application can be determined in the conventional fashion taking account of the general considerations associated with the determination of any CAR licence.

Sites where Excis is not already authorised.

At marine cage fish farm sites where Excis is not already authorised and operators are seeking to add AMX to the list of products which may be discharged or where an application is made for a new site including discharges of AMX, a different approach to that set out above is required.

In these cases applications including AMX are to be dealt with in the same fashion to the existing approaches to dealing with applications for Excis and Salmosan. Full details of how such applications should be handled are set out in the fish farm procedures manual available on QPulse, Section 5 and Annex G of the manual may be helpful here. The established approach involves applicants undertaking the collection of hydrographic data and modelling the dispersion of the medicinal product following use and discharge from the fish cages. Applicants submit modelling assessments as part of the application package and these are audited by marine science modelling staff. Given the similarity of AMX to Excis in terms of chemical structure and mode of action, the bath model used to set licence limits for Excis has been simply modified to determine licence limits for AMX.

This modelling work undertaken by applicants is used by modelling staff to produce a validated marine summary sheet detailing the amounts of each medicine that may be licensed at a given site. The values set out in the sheet are inserted into the conditions for deltamethrin, cypermethrin and azamethiphos as well as in-feed medicines as required.

Thus, dealing with marine cage fish farm applications at new sites or at sites where the use of Excis is not authorised, the process is almost identical to the determination process before the arrival of AMX. The new medicine has merely led to an additional set of figures in the marine summary sheet from which licence conditions should be derived.

4 Further advice and guidance

Further assistance with respect to this issue is available from SEPA aquaculture specialists.