AQUACULTURE STRATEGIC MANAGEMENT GROUP

SARF098 PAMP Refreshment Study – SEPA Response Options Paper

1 Background

Following the introduction of a number of sea louse medicines in the late 1990's an extensive 5 year field study was commissioned to assess whether the use of these products was adversely impacting Scottish coastal waters. The work was known as the Post Authorisation Assessment Project (PAMP) and reported in 2007.

At the time of the publication of that report it was concluded that any effect upon biological communities was no more than might be explained by the natural variability of these ecosystems over time. Due to evidence of a changed pattern of use of sea louse medicines in recent years and the possibility that this could lead to unexpected impacts SEPA sought, through the research programme managed by the Scottish Aquaculture Research Forum (SARF), to "refresh" this work to examine if the same reassuring conclusion could be reached following more than a decade of use of these products. The contract was let to the Scottish Association for Marine Science (SAMS), who had also undertaken the initial study. The project is known as SARF098 PAMP Refreshment Study.

On this occasion in contrast to the work undertaken in the last study, the work would consist of a desk based study of data held by SEPA, largely data mined from biannual monitoring studies required to be submitted by fish farm operators. The work concentrated on the possible effects of the in-feed sea louse medicine Slice (active ingredient emamectin benzoate).

The conclusions of this latest study are at significant odds with the earlier work, suggesting that sites with a history of use of Slice demonstrate impacts upon crustaceans, both in terms of diversity and abundance. The effect was seen close to the cages, at the edge of the farm "footprint" or Allowable Zone of Effect (AZE), (areas where some impact might be anticipated) and also at reference stations some distance from the farms (where no effects of fish farming, medicine use or anything else should be seen). These effects are beyond those "formally" predicted during the assessment process used by SEPA in determining applications for CAR licences but are nonetheless perhaps not that surprising given that the pattern of use of medicines has diverged significantly from that anticipated during the risk assessment for these products.

This paper examines the options for SEPA's response to the publication of this report and its findings and recommends an approach.

2 SARF098 Main Conclusions

As discussed above, the report contains a number of conclusions about the possible impact of the sea louse medicine Slice following its use on fish farms, the main points are as follows;

i) The study concludes that the use of Slice has an impact upon crustacean diversity and abundance;

ii) The impacts are seen at all distances from fish farms where the substance has been used, i.e. at the edge of the AZE and at reference stations;

iii) The impacts are not directly linked to evidence of EQS exceedance;

iv) The impact is seen at sites with "heavy" use of Slice as well as those with lower levels of use;

v) The observed effects suggest that the impact is cumulative and recovery does not occur between applications;

vi) Ultimately it is concluded that benthic crustacea are not adequately protected by the current regulatory approach.

These conclusions are arrived at through quite intense statistical analysis of the subset of the data which was able to be used and which forms part of the self-monitoring studies held by SEPA. A wide range of variables are examined to assess the potential for other factors to have caused or contributed to the observed decline in crustaceans but these are eventually all excluded.

3 SEPA's response, - what to do now?

It is our understanding that publication of the final report is some weeks away, but that this may be further delayed if SARF decide to await the findings of an additional piece of research into impacts on commercially important crustacean. SEPA therefore has an opportunity both to prepare for questions arising from the media and to ensure we have a firm position developed on our approach to the regulation of the use of Slice use on fish farms. This section provides a number of options and a brief appraisal of each of these.

i) Delay and/or denial

Option 1- Challenge the conclusions

The conclusions in the report are firm but statistically derived and therefore inevitably open to debate, however it may be possible to undertake a different analysis which would change or weaken the conclusions. This route would inevitably be controversial and as SEPA is a Director of SARF who sought for the work to be commissioned and has had input through the writing of the report and in its sign off, it would be difficult to support. This option is therefore not considered further.

Option 2 - Await the outcome of further research before taking action

The report inevitably suggests avenues for further research and indeed a further examination of the data has been approved and will be funded by SARF, this is likely to take at least 4 months to complete.

The aim of this further analysis is specifically to attempt to assess whether commercially important species have been impacted in the same way as the broad effects seen on the crustacean subphylum more generally.

It is not clear from SARF if publication of the report will be delayed until this additional research is concluded, if it was then SEPA would have the option of awaiting the finalisation of the report before taking any firm action.

While awaiting the outcome of this additional work may have merits – for example if it demonstrates no detectable effect on commercial species, it might also in some sense worsen the news – if detectable effects are shown. However, it seems likely that this work will at best prove to be inconclusive because the occurrence of commercial species in surveys tends to be very limited and drawing firm conclusions from a small dataset will be difficult.

In the event that the report is published without the additional research having concluded it is likely that the media and others with an interest in the issue will expect a more solid response in connection with the report than that SEPA is waiting the outcome of further research. For this reason delaying action would only appear to be a credible approach in the event that the publication of the whole report is delayed awaiting the additional research and even then it could be seen to be an evasive action on SEPA's part, although this time could usefully be used to further prepare our approach.

ii) Amend our approach by applying improved science

Option 3 – Vary the environmental standards used in deriving licence conditions

The current licensing approach for Slice is based upon the principal of setting limiting conditions on the rate of use of the product to ensure that environmental standards for Slice are not breached on the seabed around fish farms. SEPA further developed a sophisticated model to derive limits on the ongoing use of the product with the aim of avoiding accumulation in the sediment around farms.

Clearly, the evidence presented in the report suggests that this approach is failing in it's principal aim of protecting the environment around fish farms. The fact that the data also shows an impact at sites with low levels of use as well as those with high levels of use suggests that this is not entirely due to a "build up" of the product around farms leading to an impact.

This conclusion is at odds with the work in the original PAMP study, undertaken in the early years of use of Slice, where no impact was detectable at what was, by today's standards very low levels of use. Clearly something has changed, possibly the higher levels of use currently observed are leading to an accumulation, or the data on use provided by farmers is incomplete such that sites with apparent light use are actually subject to higher exposure levels.

The data on environmental concentrations which we have to hand and is considered in the report tends to show that there is not a direct correlation between impacted sites and EQS breaches, with many of the sites showing impacts on crustaceans not having above EQS concentrations of emamectin residues. It is a complex picture however because residue samples and biological samples are not necessarily collected at the same time. This could mean for example then that the EQS could have been breached at some point before the biological samples were taken but were found to be acceptable at the time of residue sampling.

The report also includes suggestions that in the period since the derivation of the environmental standard for emamectin that there is research evidence suggesting greater sensitivity in certain species. In addition, it suggests that as well as direct toxicity, the nature of the reproductive cycle of crustaceans may influence the impact which emamectin will have on certain species – e.g. whether they brood their young or whether they are dispersed.

The derivation of the environmental standards used by SEPA since the introduction of Slice in 1999 was robust and independently peer reviewed. Since this time however, the pattern of use has changed dramatically such that the current environmental standard should be subject to review even in the absence of the evidence presented in SARF098. This is because the current standard is effectively a Maximum Allowable Concentration (MAC). MACs are used where releases of pollutants are occasional or intermittent - perhaps once or twice per year. The original vision for Slice was that it would be used once or twice per year but currently the reality is that it is used in many sites 5-7 times per year. This fact added to the reality that residues have a half life in excess of 200 days would suggest that rather than a MAC, an Annual Average (AA) approach to an environmental standard would be more apt.

It is possible then that a review of the environmental standard for Slice should be undertaken and that this would provide a safer approach to licensing the medicine. This would include an appraisal of available toxicity studies, possible new toxicity studies plus the utilisation of this data to derive a new environmental standard based on an Annual Average approach.

Option 4 – Improve the model outputs to refine predictions of post release environmental concentrations.

It is possible, and indeed some evidence may be emerging from a recent SEPA study of Shuna Sound, that the modelling used by SEPA in the licensing approach may be underestimating far field deposition and therefore the potential effects in this area. It is possible if this effect is widespread that this would lead to an unanticipated denudation of crustaceans in the far field. It would however also perhaps lead to EQS breaches and the data in this draft SEPA study, while showing some elevated concentrations does not suggest widespread EQS breaches, this is similar to SARF098 where, as discussed above, widespread occurrence of residue levels above EQS are not reported.

Thus while the work currently being undertaken on the model suggests an under-estimate of deposition in the far field it would not appear to be giving rise to residue levels above the EQS. Thus then, if this underestimate of deposition is real, it can only be giving rise to the effects measured in SARF098 if the current EQS is inadequately protective.

The aim of the SEPA study to assess the credibility of the current version of DEPOMOD is linked to the development of a new version of the model. This work will continue and is required for the prediction of biological as well as chemical effects, it is clear however that any attempt to improve the model predictions to lessen the effect of Slice in response to SARF098 would need to be combined with a refinement of the environmental standards as discussed above.

iii) Remove or restrict the medicine

Option 5 – Reduce the access to the product for repetitive use

SEPA's current licensing approach allows an initial treatment using a set amount of Slice with the aim of ensuring that environmental standards are not breached beyond the farm footprint. Subsequent treatments at any individual site are limited by means of a calculation which takes account of the deposition of the product in waste feed, in fish faeces and its degradation on the seabed.

In essence, at a typical site, if an operator seeks to carry out a treatment soon after an initial treatment at the site, it is likely that the amount of medicine that can be used will be limited in order to provide environmental protection. While at many sites, the re-treatment calculations will limit on-going use of the product, the current profile at other sites means that lesser limitations will be imposed. Thus we see a situation where >5 treatments are often undertaken at sites during the growth cycle, in some cases, >5 treatments in the first year of production and in almost all cases, higher than standard dose rates are being used, sometimes up to 11 times the dose rate.

Beyond any errors in the EQS and the modelling outputs discussed in 3 and 4 above, this usage coupled with the long half life leads to a circumstance where the product is likely to be almost continually present in the seabed around farms. As discussed in 3 above this is not the circumstance that was envisaged when the product was first brought to market and means that a licensing system based on a MAC is not appropriate. As discussed above, this could be addressed by developing a new environmental standard based on an AA or alternatively, bringing in a more restrictive licensing system to allow a single use per growth cycle, which would mean that a MAC was the appropriate type of standard to use in licensing the product.

The report indicates an impact at reference station sites wherever Slice has been used, regardless of the quantity used, as such restriction to one use per growth cycle, whilst appearing to be an action that will reduce impact, will not necessarily be so. This option could be further developed to prevent use other than in the early stages of the growth cycle and without the existing veterinary discretion to exceed dose rate. At best this is a precautionary approach rather than a preventative approach.

Option 6 – Remove the product from use in Scottish fish farms

SEPA's aim in allowing access to limited amounts of products such as Slice, is to allow the responsible treatment of sea louse infestations for the benefit of fish farm operators and wild salmonid populations while protecting the wider environment.

Fish farming is unique in that it is a sector which is allowed to discharge substantial quantities of biocides, some of them Priority Substances in terms of the Water Framework Directive and all at least List II substances in terms of the old EU "Dangerous Substances Directive". This policy position accepts that within a limited area around each fish farm that there will be an impact upon the environment but this will be restricted both spatially and temporally. The approach is scientific, peer reviewed and generally has been robust. SARF098 calls into question the ongoing security of the current means of authorising releases of sea louse medicines, and in particular, Slice.

The situation with respect to Slice is not unique, the other systemic sea louse medicine which has been used in Scotland, Calicide (active ingredient teflubenzuron), has recently been withdrawn on SEPA's advice following higher than anticipated residues arising from the use of that product. That withdrawal occurred based purely upon the evidence of higher than EQS concentrations of teflubenzuron in the environment in the vicinity of farms. In the case of Calicide, there was no accompanying evidence of damage to biota. In this case we have evidence that at sites where the product has been used sensitive fauna has been impacted in terms of abundance and diversity.

It is possible that a substantial refinement of the approach as discussed above would once more add rigor to our licensing system, the practicality of the introduction of

such changes is discussed further below. Alternatively, given the apparent impact at a wide range of sites, even those with comparatively low levels of use, might lead to the conclusion that its use cannot be safely and practically authorised and we should seek its withdrawal like that achieved for Calicide. The means of withdrawal could be voluntary from within the Industry or be imposed by SEPA.

4 Discussion

SEPA is justifiably proud of the approaches which have been developed to model the likely effects of sea louse medicines to enable them to be released while ensuring environmental protection and generally. To date effects such as those described in SARF098 have not been evident, indeed, as discussed above, the original PAMP report demonstrated no detectable effects from the use of these medicines. In part though this is down to our not having been in a position to undertake analysis of the data that we hold and this could be seen as a significant failing on our part, especially in light of anecdotal claims of impacts on crustacean fisheries.

SEPA's regulatory approach to fish farming has been viewed favourably on a global scale and like this approach, the report and its conclusions will also be viewed at the global scale and may therefore have a significant impact on the regulatory position in other countries. The seniority of the response from MERCK, having viewed the report through SARF agreement, suggests that the report is potentially very damaging to MERCK both financially and to its reputation. Likewise, SEPA's reputation as a regulator is challenged by our response to the report.

The arena in which these products are deployed has however changed, resistance in sea lice to the available actives is not freely admitted by the sector but is evident from patterns of medicine use. Operators typically declare the use of various products on multiple occasions during each two year growth cycle, the use of 20 or more treatments is not unusual with each active ingredient being used 5 or more times. If SARF098 had not been published the nature of use of these products would have led to a requirement for SEPA to review the means of authorisation of sea louse medicines. That it has been published merely makes such a review, both for Slice and the other active ingredients all the more necessary and urgent.

If we were to progress a change in the way in which we have proceeded in the past, the evidence in SARF098 should prompt us to review the science involved in our current licensing approach. As discussed above, this would *inter alia* involve a review of the environmental standard and further development work on our depositional model. SEPA is not resourced to undertake this work and would therefore have to seek the co-operation of and investment from MERCK, the holder of the veterinary medicines authorisation for the product. MERCK have been in contact with SEPA and are keen to meet to discuss our proposed approach so this could be explored with them.

Reviewing the PNEC will involve the employment of a suitable consultant, literature reviews and probably some ecotoxicology work. This will cost a substantial sum and as the end point will inevitably be a further and probably substantial restriction on the use of what is a "mature" medicine with resistance evident in the target species, it is thought unlikely that funding would be forthcoming from MERCK. Alternatively we could seek a much more substantial and pragmatic restriction on use, probably temporally based i.e. limiting use to once per growth cycle Option 5, but without reworking the ecotoxicology to refine an environmental standard we could not be certain that this would provide any additional confidence that impacts were limited to an acceptable level.

There is a further difficulty with Option 5 and that is one of practicality from a regulatory standpoint. As discussed above, the sea louse populations appear to have developed resistance to all of the actives available to fish farm operators. Control of sea louse infestations is difficult to achieve and in some cases seems to involve almost continual use of Slice and other products through the growth cycle, particularly in the summer months when water temperatures and louse reproduction rates are high. Against that background it is difficult to see how SEPA could enforce a restriction on repetitive use, in practical terms it would be unenforceable. Proving that residue levels at a site had arisen from a single legitimate treatment rather than more than one such treatment would be very difficult and as SARF098 has demonstrated, the environmental consequences of even single treatments may well be substantial.

Thus we come to the option of withdrawing the product from use in Scotland, either voluntarily or enforced. For the reasons discussed above, it seems that this is the only practical means of securing the ongoing health of crustacean populations in Scottish coastal waters. It is pragmatic rather than scientific but given the likely difficulties of securing a scientific solution, and the likely implications of the ongoing use of the medicine, the pragmatic approach seems the most sensible. Should we secure the withdrawal of the product from use in Scotland then the occurrence of residues at fish farm sites will be clearly due to illegal use and a simpler matter in terms of enforcement than the scenario described in the paragraph above. It also follows the precedent set in terms of Calicide although the evidence in this case is actually more damning as we have a situation where the use and discharge of a chemical has led to widespread impact upon a substantial and important part of the marine benthos.

It is difficult to see how we could continue to sanction the use of Slice in the face of the evidence that is presented and in the absence of a significant programme to re-design our licensing system. Should it be proposed to undertake such a re-design, it would seem imperative to withdraw Slice from use until such time as that review was complete. As the likely outcome of the re-design will be a tighter environmental standard with likely recommendations on limits on use to perhaps once per growth cycle, the medicine would no longer be practically useable on any fish farm in Scotland.

If SEPA proposes to seek to stop the use and release of Slice, we may be subject to pressure from either the manufacturer, the industry or both to either delay or adopt another approach – perhaps one of the other options outlined above. Having said that it seems that there has been an awareness of the wider environmental impact of its use amongst the producer and some in the Industry from work undertaken elsewhere in the world. Industry representatives seem almost resigned to the loss of the product and not to be surprised at the report conclusions. It may however be argued that the loss of crustacean diversity is an acceptable cost given the benefits arising from the farming of salmon. This is not an argument that should be accepted or endorsed by SEPA as that would essentially represent a “political” decision and SEPA should not find itself in a place where we are judging between the benefits of the sector and widespread far field effects on an entire phylum of the benthos.

In addition to the concerns over the use, and over-use of Slice, the current patterns of use of the other authorised medicines should be a matter of some disquiet to SEPA. The bath medicines in use in Scotland have been authorised using environmental standards that are essentially MACs. The pattern of use of these products is however generally not intermittent but often highly repetitive, this would

seem at odds with the way in which the products have been licensed. Work is underway to review the bath treatment model and initial indications are that there is a view that it has been overly conservative.

In terms of Water Framework Directive implications, emamectin benzoate is not a priority substance with respect to the WFD. It would appear to be possible, given the current ecological means of classifying waterbodies that even if crustacean populations are substantially impacted, or indeed absent, a waterbody could still be classed as good or better. Work is currently underway to assess the classification outcome of a number of the waterbodies for which data was analysed in the report in order to clarify this point. Thus it may be possible for SEPA to state that in terms of WFD classification the impact of Slice use is insignificant, at least until any change to the classification methodology was made to reflect what was probably an unexpected impact from pollution. This is not however considered to be a sustainable position because irrespective of the position as concerns the WFD, the waters in which salmon farming is practiced are usually the same waters in which Scotland's valuable crustacean fisheries are located. Whatever conclusion is reached on the quality of such waters in terms of the WFD, it is not tenable for SEPA to adopt a position where commercial shellfish species are impacted by the day-to-day activities of fish farms, activities which SEPA will have knowingly authorised under CAR. Indeed, one of the significant considerations and drivers of the authorisation process for all sea louse medicines has been the protection of commercial shellfish species, SARF098 reveals that there is a significant risk of failure to provide such protection.

5 Recommendations

i) In light of the imminent publication of the SARF098 report it is recommended that SEPA put in train a process to withdraw the use and discharge of Slice at fish farm premises in Scotland;

ii) It is recommended that this be achieved by means of a review of all fish farm licences to delete conditions relating to Slice;

iii) It is recommended that limitations on the use of other currently authorised sea louse medicine be introduced such as their use is restricted to that which might be accepted as "intermittent". A restriction on use to one use per growth cycle would meet the terms of that definition and also promote good pest management;

iv) For all new products, it is recommended that SEPA adopt an overarching licensing policy which meets the terms of the environmental standards developed for the products and good pest management practices, so that any product cannot be used more than once per growth cycle.

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