SCOTTISH ENVIRONMENT PROTECTION AGENCY
Agency Management Team

Proposed Withdrawal of Permission to release Residues of the Sea Louse Medicine "Slice" from Scottish Marine Cage Fish Farms

1. Synopsis

1.1 This paper contains a recommendation from SEPA's Aquaculture Strategic Management Group (ASMG) to change SEPA's regulatory approach applying to the use of the "in-feed" sea louse medicine Slice (containing the active ingredient emamectin benzoate) at Scotland's marine cage fish farms (MCFF). The proposed change takes account of the changing use of this medicine, with many operators departing significantly from the maximum usage suggested in the manufacturer's label instructions, the patterns of use anticipated when SEPA developed its regulatory standards and good husbandry practice, both in terms of increasing dosage and in the frequency of treatments.

1.2 Investigations carried out by SEPA in Shuna Sound have also indicated that residues of Slice may be more mobile than originally thought, posing a risk that areas of accretion remote from fish farm sites may be at risk from toxic accumulations.

1.3 There is also evidence of subtle but more significant and widespread environmental impacts from the use of the product than originally predicted, according to research, sponsored by the Scottish Aquaculture Research Forum.

1.4 The matter needs to be considered as a matter of priority as the evidence casts some doubt that SEPA's regulatory approach remains sufficient to prevent environmental harm occurring in the marine environment with possible future consequences for Scotland's crustacean shellfish sector if action is not taken. In view of the significance of this decision, the ASMG seeks sign-off from SEPA's Senior Management level.

2. Risks

2.1 SEPA authorises the discharge of medicine residues to the environment from marine cage fish farms (MCFFs), and there are reputational risks if we do not act on research findings indicating our regulatory regime is not adequate to provide full protection of the environment.

2.2 There are also reputational risks in removing a medicine previously relied upon by one of Scotland's most important industries. Use of sea louse medicines play a part in reducing the risk of cross-infection from farmed to wild fish stocks and also helps to maintain the health and welfare of farmed stock. The issue needs to be carefully considered in line with SEPA's statutory purpose, and SEPA's decision and subsequent actions carefully explained to all interested parties.

2.3 The risks have been fully explored by SEPA's Aquaculture Strategic Management Group (ASMG).

3. Resource and Staffing Implications

3.1 If the proposed course of action is endorsed, Operations staff will require to be re-deployed to review and suspend relevant CAR licence conditions. Aquaculture Specialist staff will also require to engage with representatives of the aquaculture sector, media and other interested parties to manage expectations and explain our stance.

3.2 Further licensing implications for future development may be influenced by the withdrawal of the sea louse medicine concerned. At this stage it is not possible to accurately estimate the size of the resource required to fully manage the issue before us.

4. Equalities

4.1 There are not considered to be any significant equalities issues arising from this matter.

5. Environmental and Carbon Impact

5.1 There are unlikely to be any significant carbon implications arising from the matter in question.

5.2 The suspension of use of this sea louse medicine could have an impact on the sea louse burden on farmed salmon with possible indirect impact on wild salmonid fish stocks through an increase in the release of sea louse eggs from lice present on infected farmed fish into Scottish coastal waters.

6. Submission to Agency Board

6.1 ASMG consider that the matter set out here is a regulatory decision rightly falling within the remit of SEPA's Senior Management.

6.2 It is not anticipated that Agency Board approval is required to allow the proposed action to proceed, however, the matter should be reported to the Board in due course.

7. Recommendations

ASMG therefore seeks the endorsement of SEPA's senior management to:

1. Note the ASMG's assessment of the present problems with the authorisation of the use and discharge of the sea louse medicine Slice residues.
2. Note that an early meeting with representatives of the Salmon Farming sector has taken place by teleconference to advise them of SEPA's concerns and listen to their views.
3. Note that Aquaculture Specialists are keeping Marine Scotland colleagues appraised of the situation to ensure we can fulfil Scotland's obligations regarding our agreement with Canada, Chile, and Norway in due course.
4. Approve appropriate regulatory action to effect a managed phase out of the use and discharge of Slice on Scotland's MCFFs.
    a. It is considered that the most effective method would be to work with the VMD to effect a modification of fish vets prescription of Slice back to the maximum dose rates and frequencies set out in the manufacturer's dosage instructions;
    b. SEPA will increase its level of oversight of the use of Slice by imposing, through licence variation, a requirement for all treatments to be checked and authorised by SEPA until such time as the withdrawal takes effect;
    c. At the same time SEPA will set a date for the complete suspension of the relevant CAR licence conditions to prevent use of Slice at all fish farms in Scotland (at present we recommend a target of 2 years to achieve this phase-out, (in any event it should not exceed 3 years);
5. Agree that a media strategy be developed to provide appropriate interventions explaining SEPA's decision and actions in readiness for the publication of the SARF098 final report.

Authors: Andrew J Rosie, Head of Operations: North, Chair ASMG
Douglas Sinclair Lead Aquaculture Specialist

Sponsor: Calum MacDonald, Executive Director, (Operations Portfolio)

Date: 12th February 2016

Is this to be included in communications to all Ops staff? No

If no, please provide justification here:

The matter should be remain restricted until SEPA's position is finalised, and appropriate statements are prepared explaining the position. SEPA's Aquaculture Specialists will notify relevant staff once our course of action is agreed.

[Right aligned header - **Paper No**. (to be allocated by the Personal Assistant)]

SCOTTISH ENVIRONMENT PROTECTION AGENCY

Proposed Withdrawal of Permission to release Residues of the Sea Louse Medicine "Slice" from Scottish Marine Cage Fish Farms

Introduction

1 This paper contains a recommendation from SEPA's Aquaculture Strategic Management Group (ASMG) to change SEPA's regulatory approach applying to the use of the "in-feed" sea louse medicine Slice (containing the active ingredient emamectin benzoate) at Scotland's marine cage fish farms (MCFF). The proposed change takes account of the changing use of this medicine, with many operators departing significantly from the maximum usage suggested in the manufacturer's label instructions, the patterns of use anticipated when SEPA developed its regulatory standards and good husbandry practice, both in terms of increasing dosage and in the frequency of treatments.

2 Investigations carried out by SEPA in Shuna Sound have also indicated that residues of Slice may be more mobile than originally thought, posing a risk that areas of accretion remote from fish farm sites may be at risk from toxic accumulations.

3 There is also evidence of subtle but more significant and widespread environmental impacts from the use of the product than originally predicted, according to research, sponsored by the Scottish Aquaculture Research Forum.

4 The matter needs to be considered as a matter of priority as the evidence casts some doubt that SEPA's regulatory approach remains sufficient to prevent environmental harm occurring in the marine environment with possible future consequences for Scotland's crustacean shellfish sector if action is not taken. In view of the significance of this decision, the ASMG seeks sign-off from SEPA's Senior Management level.

Background

5 SEPA permits the release of waste residues from medicinal treatments on MCFFs to treat parasitic crustacean (sea lice) infestation. Extensive eco-toxicological and predictive dispersion modelling assessments were carried out prior to the release of these compounds being permitted by conditions in CAR licences. A safe environmental quality standard (EQS) was established for each medicine active ingredient using sound scientific principles, to ensure that any residual toxicity from the medicine residues after treatment did not pose significant risks to the surrounding water environment (including the seabed) outwith the immediate effects zone or "foot-print". Finally, SEPA sought an independent scientific peer review of the resulting EQS. Licence conditions are designed to limit release according to the environment's capacity to break it down.

6 SEPA has recently taken action to phase out another sea louse medicine called "Calicide" which has an active ingredient Teflubenzuron. This followed analytical evidence of rising residue levels in marine sediments. Following discussions with the manufacturers, they chose to withdraw the compound from the market voluntarily. Its usage was not widespread due to the limited efficacy of the product on restricted moulding stages of the sea louse's life-cycle.

Changing Use of Slice

7 Over the last 2-3 years SEPA has witnessed a significant change in the use of Slice; increases in the dosage, in terms of concentration in the feed, length of treatment period,

and frequency of separate treatments. The result is a significant change in the pattern of release from fish farm cages compared to that predicted by SEPA's risk assessment when the medicine was first authorised which was based on the recommended dose and treatment regime established by the manufacturers. Although the manufacturer's instructions permit multiple treatments, the current frequency of use was not envisaged.

8 Slice has been the mainstay of the Scottish Salmon industry for the last 10 to 15 years, however, an over-reliance on this medicine, and departure from manufacturer's treatment instructions as detailed above has apparently led to the development of drug-resistance in sea lice infecting farmed salmon, and it may now be approaching the end of its useful life as an effective medicine.

Emerging Research Findings and Residue Levels

9 SEPA's Marine Scientists have been studying tidal dispersion patterns in Shuna Sound, Argyll using a hydrographic model. The study highlighted that residues of Slice are significantly more mobile than previously thought, migrating and accumulating in areas of sedimentation remote from the fish farms in the sound. Of particular note, residues were found to be present 18-24 months after the last reported treatment had been completed.

10 Following the introduction of a number of sea louse medicines, an extensive 5 year field study was commissioned in the late 1990's to assess whether the use of these products was adversely impacting Scottish coastal waters. The research was known as the Post Authorisation Assessment Project (PAMP) and reported in 2007. At the time of the publication of the 1st PAMP study report it was concluded that any effects upon marine ecosystems were no more than might be explained by the natural variability of these habitats over time.

11 As a result of concerns over the increasing use of Slice, SEPA sought to have the PAMP study "refreshed", with funding from the Scottish Aquaculture Research Forum (SARF) following more than a decade of continuous use of these products. The contract was let to the Scottish Association for Marine Science (SAMS), who had also undertaken the initial study. The current project is known as SARF098 PAMP Refreshment Study.

12 In contrast to the largely field-based work undertaken in the last PAMP study, this "refreshment study" involved a desk-based analysis of seabed biological data submitted to SEPA by fish farm operators arising from biannual self-monitoring studies required to be carried out as a condition of their CAR licence.

13 This latest study concludes that sites with a history of use of Slice are now showing signs of impacts upon small sediment-dwelling crustaceans, both in terms of diversity and abundance. The effects appear to be occurring at concentrations below the limit of analytical detection and to be cumulative over time.

14 The apparent effects were seen close to the cages, at the edge of the farm's seabed "footprint" (this is the area of sea-bed where some impact is anticipated) and also, of significantly more concern, at reference stations some distance from the farms where no effects of any fish farming activity would be expected to be seen. These far-field impacts are beyond those formally predicted during the initial assessment process used by SEPA in determining applications for CAR licences.

ASMG Assessment

15 A full range of options were considered by ASMG:

- **Do nothing;**

16 SEPA's risk assessment of the fate and behaviour of Slice residues in the environment did not anticipate the present increased dose rates and treatment frequencies. The Shuna Sound study indicates residues are more mobile than previously thought. SEPA concerns led to the commissioning of this study as a cross-check of its own regulatory approach to permitting the use of these toxic chemical agents. The results of the PAMP study appear to provide an early warning that the environmental response is not as predicted by our earlier studies. Taking no action poses a risk to the environment and to SEPA's reputation.

- **Await the outcome of further research before taking action;**

17 While the PAMP study results pose questions which are currently unable to be answered (regarding the full implications to commercially important crustacean species for example), the Shuna Sound study and data on increasing usage provides sufficient evidence for SEPA to re-assess its regulatory approach.

- **Reduce access to the product for repetitive use,**

18 The original risk assessment did not envisage the current quantities being released into the environment. The latest evidence indicates the impacts are subtle and appear to be cumulative. It is likely that any regime derived from additional data will need to take account of the study findings with respect to repetitive treatments.

- **Re-assess the risk assessment (requiring additional toxicity and fate and behaviour studies),**

19 If the manufacturers wish to extend the permissions governing the use of Slice, SEPA will require additional data before a revised safe regulatory regime could be derived taking account of recent research.

- **Restrict permission to use/ discharge Slice, either completely, or in a phased way as a precaution while other options are explored.**

20 Its important to consider the implications. Suspension of use of the salmon-farming sector's medicine of choice for the last 10 to 15 years has the potential to pose difficulties in effective control of sea louse infestations. Should lice burdens on farmed fish increase as a result of loss of this medicine there is a threat to farmed fish welfare and a risk of cross infection to wild salmonid species migrating past the sea cages.

21 SEPA's data on usage indicates that the efficacy of Slice is now increasingly curtailed in some geographical zones as we see repetitive Slice treatments, (sometimes exceeding 5 treatments on the same year-class of fish), with the fish vets also prescribing dosage rates far in excess of manufacturer's original specifications.

122 The efficacy of Slice as a reliable medicine for treatment of sea lice appears from this to be diminishing, and the sector is already developing strategies to control lice using means other than dosing with medicines.

23 Recent visits to Norway by SEPA officers indicate that there are an increasing number of alternative and effective non-chemical control methods becoming available, with

more in development. These include the use of “cleaner fish” (wrasse and lump-suckers) deployed in the salmon cages which eat the sea lice from the bodies of the passing salmon. Physical barrier techniques to reduce or prevent infective stages from reaching young farmed salmon, and novel techniques for physically removing them are also well advanced, including inducing the salmon to swim through a freshwater layer and destroying lice on salmon using a laser beam.

24 It is therefore crucial, given the outcome to the present, study that SEPA works closely with the sector to develop alternative strategies which allow the sustainable future development of this important Scottish industry without reliance on chemical therapeutants, while providing adequate environmental protection. ASMG proposes that we instigate early discussions to promote adoption of these innovative techniques.

25 Slice has been the medicine of choice for all salmon-farming nations around the world and this year Scotland’s Minister for Environment signed an agreement with her counterparts in Canada, Chile, and Norway to cooperate in promoting the growth of sustainable aquaculture. It is possible, faced with the prospect of adverse publicity arising from the changing use of the product, and the likely publication of the PAMP study report, that MSD Animal Health may choose to withdraw Slice from sale. While that is entirely a matter for them, the impact of such a decision may be limited to the Scottish market or may impact on an international scale. The ASMG consider it appropriate to share, via our Marine Scotland colleagues, details of the PAMP study to alert the relevant agencies in each of the “partner” countries.

Proposed Way Forward

26 The new evidence poses sufficient challenge to SEPA’s understanding of the fate and behaviour of Slice residues to render SEPA’s reliance on the present regulatory regime unsafe.

27 Taking account all the factors, including the importance of this medicine to the Scottish Fish Farm sector and its role in reducing risk of sea lice cross-infection of wild fish stocks, ASMG recommend that action is taken to restrict use of Slice that deviates significantly from the manufacturer’s instructions as a matter of priority, and to impose a withdrawal of Slice to safeguard the wider environment and commercially important species such as prawns, crabs and lobsters while any proposal by its manufacturers to reinstate treatments is carefully considered.

28 This withdrawal needs to be phased, as an immediate ban poses a risk of sea lice burdens increasing and cross-infecting wild salmonid stocks. An immediate ban might also be considered unreasonable as there are sites which are currently stocked or are about to be stocked based on operators’ the understanding that Slice would form part of the arsenal of defences against sea lice. Growth cycles at Scottish Salmon farms generally last for about 2 years. A phased withdrawal also allows the industry a chance to develop alternative lice control strategies and invest in appropriate new equipment without the need to rely on Slice treatments. At this stage the ASMG consider the target timeframe for this phased withdrawal should be 2 years, (and in any event should not exceed 3 years).

29 In the interim period before the withdrawal becomes effective SEPA will increase its level of oversight of the use of Slice by imposing, through licence variation, a requirement for all treatments to be checked and authorised by SEPA. This will allow use and subsequent discharge to be restricted at those sites where we have evidence of seabed impacts from its use to date but will not impact on sites where these impacts are not apparent.

30 SEPA will also engage with the Veterinary Medicines Directorate (VMD) with a view to developing an aligned approach; seeking their assistance to moderate fish vets prescribed use back more in line with the product label instructions.

31 SEPA officers therefore met representatives of the manufacturers, – MSD Animal Health, to discuss recent findings, explain SEPA's concerns. MSD representatives noted SEPA's concerns, but reserved their position, expressing a keenness to maintain a dialogue with SEPA while they consider their options and discuss the issue with the industry and the VMD. Only if SEPA receives sufficient evidence that the treatment regime could be amended in a way that offered efficacious treatments to farmed salmon and protected the environment from subtle but damaging impacts, would ASMG advise the re-introduction of Slice to CAR licences.

SEPA's Response to Media Enquiries

32 The environmental impacts resulting from marine cage fish farming and the risks posed by chemicals and medicines used by the industry has been a subject of interest to the media and certain NGOs in Scotland for many years.

33 While publication of SARF098 is likely to attract interest from these parties, SEPA's regulatory approach has throughout been informed by the best scientific knowledge available at the time, and, even after approving the use to this compound, has still sought scientific safety checks to be commissioned to look out for early warning of any unexpected outcomes. The results of this 2nd study indicates just that; the ASMG recommendation is an objective and measured response to concerns over increasing dose rates and the subtle signs of environmental impact, even when the compound is not detectable in seabed sediments by sophisticated chemical analysis.

34 In advance of the publication of the report, it is proposed that SEPA's Aquaculture Specialists will work with Communications staff to prepare statements for the media explaining why SEPA feels it necessary to take this restrictive course of action, with potential impacts on Scotland's salmon farming industry.

Conclusion and Recommendations

35 ASMG therefore seeks the endorsement of SEPA's senior management to:

I. Note the ASMG's assessment of the present problems with the authorisation of the use and discharge of the sea louse medicine Slice residues.
II. Note that an early meeting with representatives of the Salmon Farming sector has taken place by teleconference to advise them of SEPA's concerns and listen to their views.
III. Note that Aquaculture Specialists are keeping Marine Scotland colleagues appraised of the situation to ensure we can fulfil Scotland's obligations regarding our agreement with Canada, Chile, and Norway in due course.
IV. Approve appropriate regulatory action to effect a managed phase out of the use and discharge of Slice on Scotland's MCFFs.
    a. It is considered that the most effective method would be to work with the VMD to effect a modification of fish vets prescription of Slice back to the maximum dose rates and frequencies set out in the manufacturer's dosage instructions;
    b. SEPA will increase its level of oversight of the use of Slice by imposing, through licence variation, a requirement for all treatments to be checked and authorised by SEPA until such time as the withdrawal takes effect;

c. At the same time SEPA will set a date for the complete suspension of the relevant CAR licence conditions to prevent use of Slice at all fish farms in Scotland (at present we recommend a target of 2 years to achieve this phase-out, (in any event it should not exceed 3 years);

V. Agree that a media strategy be developed to provide appropriate interventions explaining SEPA's decision and actions in readiness for the publication of the SARF098 final report.

Authors: Andrew J Rosie, Head of Operations: North, Chair ASMG
Douglas Sinclair Lead Aquaculture Specialist

Sponsor: Calum MacDonald, Executive Director, (Operations Portfolio)

Date: 12th February 2016