

Consultation Response

Mowi Scotland

New environmental quality standard (EQS) for emamectin benzoate (Embz): consultation on the implementation timescales.

Executive Summary

Slice® is a medicated feed premix for the treatment and prevention of sea lice infestations in salmon effective against all parasitic stages of sea lice (*Lepeophtheirus sp.* and *Caligus sp.*). Emamectin benzoate (Embz) is the single active ingredient in Slice® with the medicine being a key and effective management tool for controlling sea lice levels on farm raised salmon.

The proposed Environmental Quality Standard (EQS) for emamectin benzoate, if implemented, will drive lower permitted levels of the medicine and in some cases will result in non-viable treatment allowances to the detriment of the welfare of farm raised salmon and removing the protective secondary benefits the medicine provides in terms of protecting wild salmonids.

Mowi Scotland wish to state at the outset that we do not support the implementation of the proposed environmental quality standard as we have significant concerns with the underpinning principles on which it has been developed.

The consultation proposes the implementation of a new, significantly lower EQS for Embz however comments on the development of the standard or the science underpinning it are not being sought. We do not believe that there are valid reasons for separating implementation policy from the science behind the new standard; in this instance the science is very relevant to discussion on how any change to the EQS should be implemented and we firmly believe that the derivation of the EQS should have been the subject to a prior and separate consultation.

Whilst the risk of impact of Embz on non-target species must be considered within regulatory controls the available evidence on such impacts have been misrepresented and consistently overstated. Additionally, the inclusion of ecotoxicological studies on freshwater insects within the derivation of the sediment EQS has driven an extremely precautionary and disproportionate approach. The evidential basis for the presence of freshwater insects and records of them residing in the marine environment is extremely limited. Mowi supports a precautionary approach to the discharge of Slice®, but not an over-precautionary reaction that removes a valuable medicine for the purposes of sea lice control, which has benefits for the health of farm raised salmon and the protective benefit the medicine offers in respect of managing the risk of wider adverse interactions with wild salmonids, in order to offer nominal protection to an insect species that is not even found in the vicinity of marine fish farms.

Any environmental quality standard used in the regulation of salmon farms must be based on the environments where the farms are located and be protective of species that are relevant and present in those locations.

It is our position that the proposed EQS should not be introduced as proposed in the consultation.

The evolution of the development of the EQS has been a low point in the regulation of the sector by SEPA and has been driven by a need to appease activism which has significantly misrepresented the environmental effects of Embz on non-target species. We do not believe it is appropriate that examination of the suitability of the proposed EQS for the purposes of regulating marine fish farms should be excluded from the consultation.

In terms of development of new regulations relating to fish farming in the marine environment, we are increasingly seeing a lack of coherence with the development of new regulatory controls being frequently contradictory in purpose. For instance, this consultation comes at a time when SEPA is presently consulting on the design and implementation of the new sea lice risk framework (SLRF) which will introduce prescribed limits on sea lice levels on farm raised salmon. The environmental driver for the SLRF is species protection (wild salmonids, seatrout, and freshwater pearl mussels) yet the consequence of the proposed EQS will be the reduction or loss of access to an effective sea lice medicine.

The introduction of the new environmental standard for emamectin benzoate will result in a loss or reduced access to a proven effective medicine for sea lice. This is being proposed at a time whilst simultaneously implementation of the Sea Lice Risk Framework will result in the requirement for increased sea lice treatments to comply with a regulatory threshold. It is unclear how the Scottish Government and SEPA intend to balance these two conflicting interests, or whether this has even been considered.

The impact of implementation of the new environmental standard and the subsequent loss of use of the medicine **will be significant** for Mowi in terms of controlling sea lice infestation pressure and managing the health and welfare of our salmon.

Any change to the existing EQS should not be implemented until there is a suitable alternative, which provides the same, wide-ranging benefits that are available from a long acting, in-feed sea lice medicine such as Embz. An alternative, proportionate and evidence-led approach is presented in this response, encompassing the range of actions and strategies that would be needed to mitigate for any loss or reduced future access to Slice® and the resulting business impacts and loss of an important species protection measure that would follow. These are outlined in the following sections, the mitigation strategies will require detailed investigations, will be costly and require to be implemented over an appropriate investment horizon. We would suggest an implementation period equivalent to three production growth cycles, namely (6 years) would be a reasonable and proportionate period.

Introduction

We wish to state that we believe the scope of the consultation has been too narrow. The subject matter and the potential implications that might arise from implementation of the proposed EQS **are significant**. We are concerned that the structure of the consultation does not allow the opportunity to present our concerns of the derivation of the proposed EQS or to fully address the business and environmental consequences of the implementation of the

proposed EQS. Given the extremely limited focus of the consultation and the three restricted questions on which information is requested we have chosen to expand our response to provide detail on key areas of our concern, as follows:

- Impacts on farm fish health and welfare through reduced / loss of access to Slice®.
- How long it would take to implement adjustments to sea lice management because of any changes to the Environmental Quality Standard?
- Derivation of the proposed Environmental Quality Standard.
- Application of the proposed Environmental Quality Standard in regulation on a one size fits all basis.
- Consequences of Mis-aligned regulation:
 - Environmental Implications
 - Implementation Impacts on managing interactions with wild salmonids and protected species.
- Need for a holistic review of access to existing sea-lice medicines.
- Timescales for the Implementation of any future changes to the EQS.

Impacts on farm fish health and welfare through reduced or loss of access to Slice®

Mowi Scotland uses Slice® mainly in farm raised salmon during their first 6-8 months at sea (from 150g to 2Kg) to prevent sea lice settlement and development on fish; this is a requirement to ensure good health and welfare of our stock while complying with our licenses and certification standards. The new environmental standard and subsequent reductions in permitted allowances of Slice® or a worst-case scenario, the loss of viable treatment amounts of the medicine, will significantly impact on our capacity to control sea lice (both *Lepeophtheirus salmonis* and *Caligus elongatus*.) in our seawater sites.

Mowi sea lice management practices are primarily targeted at the sea louse species *Lepeophtheirus sp.*; however, we are also experiencing an increasing challenge in the effective control of *Caligus sp.* arising from localised rises in stocks of migratory pelagic fish species in west coast waters. Being a small sea-louse species, they do not do appreciable damage to a fish unless present in very high numbers. We will proactively intervene to control *Caligus* if numbers on the farm fish are trending sharply upwards. These lice can be controlled by conventional treatment methods, but if the challenge due to prevalence on wild fish is high, then re-infestation can often occur immediately post treatment.

The preferred treatment for *Caligus sp.*, is Slice® (Emamectin benzoate); this is a high efficacy in-feed medicinal treatment that avoids the need to handle the fish. It is a treatment method that provides residual protection and is an especially important sea lice management tool when smolts are introduced to sites in late Summer/ early Autumn, this being the time when levels of *Caligus sp.* on wild pelagic fish stocks are high.

Slice® is the only licensed in-feed medicine available to the sector for treating sea lice on farm raised salmon. At the moment, the only other alternative medicinal treatments to Slice® we have available are azamethiphos and deltamethrin based products (applied as bath treatments). Supporting sea lice management tools include use of freshwater, mechanical treatments, and biological control through use of cleaner fish. These alternatives, while

effective, each have their own limitations in use which are summarised further below.

- With suitable permit limits, licensed bath medicine products containing Azamethiphos, have proven efficacy for *Lepeophtheirus* sp. However, where restrictive 3-hour permit limits exist, we cannot effectively treat many of our sites especially those which have transitioned to larger pens (160m circumference). In addition, Azamethiphos cannot be used when water temperatures are >12 °C (from June until November) without risking compromised salmon health.
- Deltamethrin based bath medicine products can be used against *Caligus* sp. with proven efficacy, where permit licenses allow, however the medicine has low efficacy against *Lepeophtheirus* sp. Similarly, as for Azamethiphos, bath treatments during summer months are not an option due to higher water temperatures.
- Freshwater can be used for sea lice control however well boat bath treatments must last for at least 10-12 hours to be effective which is not always a suitable alternative due to logistics and capacity given that it takes up to 30-35 hours to generate a full well boat load of freshwater using our current reverse osmosis systems. In addition, such long bath treatments can impact on the welfare and health of our salmon, and it can result in mortality in our deployed cleaner fish. The use of stored natural freshwater is an option including its use for the continual lensing of pens however Mowi does not have the number of required abstraction licenses in place in Scotland to strategically implement the use of natural freshwater resources. A scoping exercise has been carried out by Mowi looking for new freshwater abstraction locations. However, there are many regulatory and locational constraints in identifying appropriately sized watercourses with suitable safe access for navigation by large vessels. In addition, the sourcing of natural freshwater during the summer months is increasingly problematic especially given the recent warmer summers which does not allow enough freshwater to be abstracted to allow effective treatments to be performed.
- Finally, we would highlight that while a range of mechanical treatments are available, they cannot be used in fish recently transferred to sea and therefore is not a viable option to control sea lice in fish <1 Kg. Importantly, these treatments are also subject to fish health constraints and cannot be used in all our fish populations. Reduced or loss of access to viable Slice® allowances will inevitably drive more physical handling events for farm raised fish with resulting welfare negative consequences, including higher mortality. Avoiding fish handling is especially important with smolt input and maximising survival in the first 30 days at sea.

The fish farming sector currently has access to an extremely limited number of medicinal treatments to treat our salmon for infestation of the two sea louse species that attack the fish. For any integrated pest management programme, to maintain efficacy of treatment for each medicinal product and to prevent resistance, it is essential that their use be rotated and that repeat treatments with the same active ingredient are minimised. Slice® is a key component within Mowi's integrated sea lice management strategy, **there is no comparable alternative.**

Previous iterations of a lower EQS for Embz, introduced as interim measures by SEPA have impacted on the ability of some Mowi sites to secure a viable Slice® consent, not even permitting a single strategic treatment (per growth cycle). We therefore have experience of

the impact loss of access to the medicine has had on our ability to manage sea lice at a small number of sites, forcing the repeated use of the limited alternative medicinal treatments that are available. This impact will be multiplied many times across Mowi's full suite of farming locations should the proposed EQS be implemented as outlined in the consultation.

The impacts on farmed fish welfare **must be central** to any decision on implementation of a revised EQS for Embz. This consultation is unfortunately continuing evidence of the absence of any consideration for farmed fish welfare in the policies and regulatory approaches for fish farming developed and implemented by Scottish Government and its principal regulator, SEPA.

How long would it take to implement adjustments to sea lice management practices required because of these changes?

For the reasons explained above, the proposed Embz EQS would result in significant impacts on our ability to control sea lice and alternative control methods are not in place and will require time to develop and implement. However, it is also realistic to state that no new medicinal treatment options will become available in the coming years without regulatory support.

To implement more broadly freshwater as a viable option against sea lice, we will need to design and acquire new well boat capacity, new freshwater reverse osmosis systems which are more efficient and/or new freshwater abstraction licenses and lensing capacity.

There is no alternative licensed medicinal product that delivers the same level of sea-lice management control to that provided by Slice®. The implementation of any changes to the EQS for Embz should only occur in parallel with the development timelines for either a suitable alternative medicine or alternative sea-lice mitigation strategies that deliver like-for-like benefits comparable to those provided by Embz. Considering investment horizons, especially associated with well boat design, build and commission we would consider that the implementation time frame for the range of mitigation strategies that will be required to deliver like-for like benefits would be a minimum of 6 years.

Derivation of the new Environmental Quality Standard

The consultation sets out the background and rationale for the proposed change to the EQS for Embz, the starting point being the 2016 report by SAMS that concluded the use of the medicine may be impacting on crustacean species. The evidence from this study was, however, far from conclusive with the report authors themselves recommending further research was required to establish any causal relationship between Embz sedimentary concentrations and crustacean assemblage change. Subsequent field studies were undertaken by both SEPA and the product owner of Slice® (MSD) but none of the findings presented clear evidence of significant environmental effects through the controlled use of Slice®. The data obtained consistently demonstrated the difficulty in attempting to assess the influence of a single variable, namely Embz sedimentary residues on non-target crustacean species, which are exposed to and influenced by many other environmental factors that also have an impact of the structure of the benthic faunal community.

Whilst the risk of impact of Embz on non-target species must be considered within regulatory controls, the available evidence on such impact has been frequently over-stated and used as a justification by SEPA to drive a need for regulatory action that is neither balanced nor proportionate.

While new toxicity data sets on relevant marine test species were considered as part of the UKTAG EQS review, a remaining embedded driver in the evolution of the new standard since 2016 was in the inclusion of toxicity data on freshwater species. The justification for using the freshwater data in the development of the new standard appears to be that insects with marine intertidal aquatic larval stages are known in the UK. To the best of our knowledge the use of toxicity assessments on insect larvae as a proxy for the marine environment in the setting of a marine sediment EQS has not been done before. At no point in previous regulatory dialogue with the sector have SEPA identified insects as a species of concern in the benthos around marine fish farms.

The presence of any marine insect would be rare and limited to the intertidal zone of an inshore waterbody. It can be concluded, with high levels of confidence, that they are not part of the active community in the benthos for fully marine environments. Insects do not feature in the benthic samples the sector collects as part of regulatory compliance and if encountered they would be reported in monitoring submissions to SEPA (this is a requirement as part of the Northeast Atlantic Marine Biological Analytical Quality Control scheme and is also taxonomic good practice).

We are strongly of the opinion that the introduction of any new sedimentary EQS for Embz into the regulatory structure for fish farms must be based on the risk of impacting species that are likely to occur in that environment. All available evidence supports the conclusion that insects are an extremely rare occurrence in the marine environment.

There are significant fundamental issues with the underpinning principles that lie behind the development of the proposed change to the EQS. We especially do not believe there is a justification for the application of the proposed EQS to fish farms that are sited in an open sea or `fully marine` environment. For such locations, the evidence presented to UKTAG would support the derivation of a saltwater sediment EQS based upon the most sensitive saltwater species ecotoxicological data.

Application of the new Environmental Quality Standard in regulation on a one size fits all basis.

Using an EQS that is designed for all marine and transitional waters, as the basis for protection against the activities of marine fish farming is disproportionate. We **do not support** a "one-size fits all approach and believe that use of a fully marine relevant sediment EQS should be considered where there is no risk of intertidal zones being impacted by Embz use on finfish farms. The UKTAG report acknowledges that "*environments not normally surveyed for the regulation of a fish farm are in scope of a marine EQS (note in this regard an EQS's protection goal doesn't dictate a particular regulatory strategy, nor does it have a bearing on survey strategies for regulation).*" This is implicit recognition that the proposed EQS may not be

appropriate for the environments where fish farms are located and that **derivation of an EQS does not dictate a method of regulatory implementation.**

Considering the extremely low risk to intertidal insects, an initial desk-based risk screening of Mowi sites has been undertaken examining location and proximity of mixing zones that may have the potential to interact with the intertidal zone. This has identified that approximately sixty-eight percent of Mowi fish farms are either located in open sea locations or in locations with low risk of interacting with intertidal zones that are muddy / sandy in nature, by implication where marine insects may in theory exist, and where Embz might accumulate. Such results are indicative with each farm site location representing different hydrodynamic conditions and bathymetry which will influence the potential for resuspension and transport of sediment associated Embz, however it does provide a justification for further detailed assessment on the potential use of a relevant marine sediment EQS.

We would invite the Scottish Government to direct SEPA to engage collaboratively with the sector to develop an evidence-based rationale for the identification of sites which can be considered `fully marine` environments where a marine sediment EQS can be safely introduced.

Consequences of Mis-aligned regulation

o Environmental Implications

Slice® is the only licensed in-feed medicine available for the control of sea-lice on farm raised salmon. It is used strategically to support the health and welfare of farm raised salmon by managing juvenile lice settlement during the first year of production. As detailed earlier in this response, its application as in-feed medicine means it is less impactful on the health and welfare of fish than alternative topical medicines or mechanical treatments. The alternative control measures all involve welfare negative fish handling events that have the potential for adverse effects on fish health and welfare.

A loss of access to Slice® or the reduced ability to prescribe viable treatments will lead to an increased use of the limited suite of alternative medicinal products resulting in an increase in their discharge to the marine environment. Whilst such treatments will still comply with respective EQS for the medicines concerned, the increased use (and release) of medicines to the marine environment is undesirable as a general principle. The need to demonstrate medicine minimisation is a CAR permit requirement, further evidence of the lack of a coherent regulatory approach.

There is no available and comparable medicinal product offering the equivalent benefits to Slice®. There is no evidence that the issue of medicine minimisation (and effects on efficacy of alternative medicinal products) has been considered as part of the proposed implementation of the proposed Embz EQS.

- **Impacts on managing interactions with wild salmonids and protected species.**

Consideration of the protective benefits that Slice® offers on managing the risk of adverse interactions between sea lice from farm raised fish and wild salmonids, and their role in the distribution and viability of freshwater pearl mussel populations is a relevant consideration in discussing the **unintended impacts** of the proposed Embz EQS.

Atlantic Salmon populations are in acknowledged decline and freshwater pearl mussel populations are similarly recognised as being in a critically endangered condition across Scotland. While there are a wide range of recognised pressures that are impacting wild salmon, sea lice from salmon farms are identified as one such contributing pressure. The stated purpose of SEPA's proposed sea lice risk framework is to *contribute to the (i) protection of one of Scotland's most iconic native species, the wild Atlantic Salmon and (ii) critically endangered freshwater pearl mussels and of sea trout.*

Mowi takes a responsible and pro-active approach to its environmental stewardship obligations in respect of wild salmonids. At present twenty-three of our fish farms are covered by Environmental Management Plans which provide frameworks for collaborative working relationships with wild fish partners, including the sharing of information, the commissioning of meaningful and well-designed wild fish monitoring surveys and the use of resulting data from farm raised salmon and wild salmonids in adaptive management site discussions. Several Mowi EMP's also include an obligation to undertake protective measures for local populations of FWPM and Special Areas of Conservation designated for Freshwater Pearl Mussel Populations.

The availability and strategic use of Slice® is a key tool which supports our commitment to protect Atlantic salmon by taking a precautionary approach to maintaining low sea lice levels on farm raised salmon during the key spring wild salmon / sea trout smolt migration period. Slice® is an essential medicinal product ideally placed for achieving this goal, providing extended protection, and preventing juvenile lice settlement.

There is no comparable medicine to Slice®. A loss of access to Slice® or reduced ability to undertake treatments that protect farm raised salmon from sea lice during this key smolt migration period will mean that it will not be possible to deliver the same level of precautionary protection for populations of wild salmonids.

The outcome of the consultation on the new Embz environmental quality standard will be contrary to the purpose of the sea lice risk framework and will result the reduction or removal of access to Slice®, a proven effective medicine for controlling sea lice levels on farm raised salmon. This in turn will impact on the important secondary environmental contribution the medicine offers for the protection of wild salmonids and the contribution healthy populations provide in maintaining our endangered populations of freshwater pearl mussels.

Prior to implementing any change in the Embz EQS, the potential impacts on wider species management must be given full and proportionate consideration and should be appropriately balanced with the evidence of Embz impacts on non-target crustacean species within the benthos communities around fish farms.

Need for a holistic review of access to existing sea-lice medicines.

Given the limited suite of licensed fish health medicines that are presently available for controlling sea lice on farm raised salmon it is appropriate that with any policy decision to remove or reduce access to a medicine this is accompanied by a review of access and use of the remaining two available sea lice medicines. Such a commitment is an embedded recommendation of the Salmon Interactions Working Group.

Recommendation 1.3 of the Salmon Interactions Working Group Report: **‘The Scottish Government should holistically assess and review the approach to sea lice treatment, including access to medicines and the use of controls, to deliver an evidence-based approach to sea lice control, whilst ensuring the protection of the wider environment and wild and farmed fish health and welfare.’**

We would especially highlight that licensing practices relating to use of Azamethiphos based bath products frequently generate regulatory controls that prevent the efficient use of the medicine, and in a number of cases prevent any viable pen level treatments from being implemented. While advances in predictive modelling have allowed greater confidence in the setting of limits that protect the 72-hour EQS, the continuing approach to setting limits that protect the 3-hour EQS has not been subject to review. We are faced with a scenario where we receive permits containing a 24-hour condition limit on Azamethiphos use that permits a single pen level treatment per day, only to have a conflicting 3-hour permit condition limit that prevents a viable efficacious pen level treatment from being implemented. As the industry continues to evolve by transitioning to larger pens licensing practice around the setting of limits to protect the 3-hour EQS is not evolving in parallel and is still based on principles developed in 1998.

We understand the need for precaution in respect of the setting of permit conditions relating to the use of medicines and their release into the marine environment. However, this needs to be balanced with avoiding an unnecessarily restrictive approach that inhibits the efficient and responsible use of medicines.

We would request that any policy decision to reduce access to Slice® should also be accompanied by a wider review of access to the remaining available sea lice medicines and the use of controls in their use, to ensure a holistic evidence-based approach to sea lice control is in force. We would welcome a Scottish Government direction to SEPA on this overdue issue.

Timescales for the Implementation of any future changes to the EQS

Whilst we acknowledge the potential risk to non-target species that may be posed from the use of Embz, evidence of demonstrable impact from the activities of fish farms has been overstated, including, regrettably within the consultation document. We are however supportive of the development of a scientifically derived EQS for Embz, with suitable precaution, that is appropriate for use in the regulation of Scottish fish farms. Any change to the existing EQS should not be implemented until there is a suitable alternative, which provides the same, wide-ranging benefits that are available from a long acting, in-feed sea lice medicine such as Embz.

Noting the preceding comment and evidence presented within this consultation response we would suggest that a minimum phased six-year implementation would be required to accompany any change to the EQS for Embz. This would provide for the following actions and strategies to be implemented:

- (i) To provide sufficient time for the development and implement of alternative medicinal and non-medicinal mitigation strategies for controlling sea lice on farm raised salmon.
- (ii) To ensure continued and targeted use of Slice® for controlling sea lice levels on farm raised salmon while the new sea lice risk framework is implemented.
- (iii) To support the continued protective benefits Slice® provides to wild Atlantic salmon, seatrout, while new sea lice mitigation strategies are developed.
- (iv) To allow time for regulatory discussions on the use of a `fully` marine EQS for Embz and the evidence base that would be required to identify candidate marine sites and support the safe and robust application of such an approach; and
- (v) To allow for a full review by SEPA of licensing practice around the limited suite of available sea-lice medicines in line with the recommendations of the Salmon Interactions Working Group.

Concluding Remarks

As stated in this response we do not support the implementation of the proposed environmental quality standard for the reasons highlighted throughout this response, specifically:

- **We have significant concerns with the underpinning principles on which the proposed sediment EQS has been developed. The inclusion of ecotoxicological studies on freshwater insects within the derivation of the EQS has driven an extremely precautionary and disproportionate approach. The evidential basis for the presence of freshwater insects and records of them residing in the marine environment is extremely limited.**
- **Any environmental quality standard used in the regulation of salmon farms must be based on the environments where the farms are located and be protective of species that are relevant and present.**
- **Whilst the risk of impact of Embz on non-target species must be considered within regulatory controls, the available evidence on such impact has been frequently overstated and used as a justification by SEPA to drive a need for regulatory action that is neither balanced nor proportionate.**
- **The evolution of the development of the EQS has been a low point in the regulation of the sector by SEPA and has been driven by a need to appease activism which has significantly misrepresented the environmental effects of Embz on non-target species.**
- **We do not believe it is appropriate for Scottish Government to adopt the UKTAG EQS recommendations without any further consideration of its suitability as a regulatory control mechanism for the activities of marine fish farms.**

- **The introduction of the proposed EQS for Embz will result in a loss of access to a proven effective medicine for sea lice. This is being proposed at a time whilst simultaneously implementation of the Sea Lice Risk Framework will result in the requirement for increased sea lice treatments to comply with a regulatory threshold. This is contradictory and evidence of a lack of coherence in the development of new regulatory controls that are being applied to the sector.**
- **There is no comparable medicine to Slice®. A loss of access to Slice® or reduced ability to undertake treatments that protect farm raised salmon from sea lice during the key smolt migration period will mean that it will not be possible to deliver the same level of precautionary protection for populations of wild salmonids.**
- **Prior to implementing a change in the Embz EQS, the Scottish Government must take a proportionate and balanced approach to environmental protection including the impacts the loss of access to Slice® will cause to wider species management.**
- **Any reduction in a farmer's ability to use Embz will have unintended negative consequences on the environment, through the increased use of alternative medicinal interventions.**
- **The impacts on the health and welfare of farm raised salmon must be central to any decision on the implementation of a revised EQS for Embz. There is no evidence that this has been considered.**

Finally, we do not believe that the approach outlined in the consultation aligns with the requirements of the Scottish Regulators' Strategic Code of Practice as it is not representative of a targeted, proportionate, risk and evidence-based approach to regulation.

Mowi Scotland
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