New environmental quality standard (EQS) for emamectin benzoate (EmBz): implementation timescales

Analysis of responses

June 2024

Scottish Government
Riaghaltas na h-Alba

Executive Summary

In December 2022, Scottish Ministers accepted the UK Technical Advisory Group's (UKTAG) recommendation on a new Environmental Quality Standard (EQS) for emamectin benzoate. Emamectin benzoate is used widely in medicated feed by marine fish farms to control sea lice. Ministers also approved a public consultation on the timescale for implementing the new EQS in existing farms licenced under previous EQS thresholds. The consultation was launched in April 2023 and closed on 24 July 2023. In order to address concerns expressed by the fish farm industry whilst also balancing these with a requirement to protect the environment, Scottish Ministers will direct the Scottish Environmental Protection Agency (SEPA) to implement the new EQS when the Directions come into force. SEPA will work with the operators of fish farms to implement the new EQS level based on the individual circumstance of each fish farm site.

Twenty five responses were made to the consultation from across the fish farm industry, regulators, interest groups, and individuals. There were opposing responses to many of the questions reflecting the different perspectives of those engaged in discussions about aquaculture. The consultation responses have been analysed and considered in making our final guidance on the implementation of the revised EQS for emamectin benzoate.

Given the concerns raised by the sector, and whilst balancing these with a requirement to protect the environment, Scottish Ministers will direct SEPA to vary existing licenses to implement the new EQS in 48 months. SEPA will work with the operators of fish farms to make the improvements or mitigate the effects on their operations of doing so.

Purpose

This document summarises Scottish Government's analysis of the consultation responses received about the implementation timescales for the new Environmental Quality Standard (EQS) for emamectin benzoate. The EQS regulates the quantity of emamectin benzoate used to control sea lice in marine fish farms in Scotland.

Background

EQSs set limits on the concentration of pollutants in water. They set the maximum allowable concentration of a substance in water and are key to the protection of the water environment and the achievement of our River Basin Management Plan objectives. They underpin assessments of whether waters are at risk of deterioration and what improvements would be needed to improve the status of waters that are not at good status.

In 1999, SEPA undertook a risk assessment of emamectin benzoate in the marine environment following its use for control of sea lice infestations on farmed salmonids in the marine environment. As part of this risk assessment, the Scottish Environmental Protection Agency (SEPA) derived an EQS for emamectin benzoate in sea water and sediment. The standard was 763 ng/kg of sediment (wet weight). [1]

In 2016, on the basis of accumulated scientific evidence, SEPA requested the UK Technical Advisory Group (UKTAG) to determine if the EQS derived in 1999 remained scientifically valid and, if required, to develop recommendations on a new EQS for emamectin benzoate.

UKTAG is a partnership of technical experts from the UK's environment and conservation agencies. It was set up jointly by the devolved administrations to provide scientific advice on EQSs and other matters relating to the protection of the water environment.

EQSs are developed by UKTAG to be protective of all species that may be at risk. For example, aquatic animals and plants, sediment-dwelling organisms, or predators that feed on aquatic organisms. In developing the new EQS, UKTAG used the best available scientific information and followed the latest EU protocols for deriving an EQS. As well as UKTAG undertaking its own consultation, an expert independent peer review was also carried out to ensure that proposals were scientifically valid, and that the data used to derive them were sound and complete.

Whilst the new EQS was being developed by UKTAG, SEPA applied the precautionary principle by adopting an interim EQS. This interim EQS only applied to new fish farm applications, or applications to increase discharges at existing fish farms.

UKTAG published its recommendations following independent scientific peer review in July 2022, recommending a new EQS for marine sediments of 131 ng/kg sediment (dry weight). Ministers agreed to adopt the new EQS for emamectin benzoate whilst acknowledging the possible risk to farmed fish health resulting from reducing the allowable amount of emamectin benzoate. Ministers also agreed to run a public consultation to gather views on an appropriate implementation period for the new

EQS on fish farms with an existing license in order to reduce these additional risks whilst also considering business impact.

In January 2023, UKTAG notified the Scottish Government of a possible error in the calculation of the derived EQS. Subsequently the Scottish Government paused the launch of the consultation. This allowed UKTAG to investigate further and in March 2023 they published a corrected value for the EQS. This changes the EQS from 131 ng/kg dry weight to 272 ng/kg dry weight. UKTAG published an updated report in March 2023.

Upon publication of the new EQS SEPA began applying it to all licence variations and new applications to protect the water environment from deterioration.

Our consultation sought views on the implementation timescales of the new EQS. Specifically we asked for:

Views on what timescales people and organisations consider to be most appropriate for the implementation of the new EmBz EQS and why, for example, 0, 24 or 48 months.
Evidence on how long it might take to implement any adjustment to sea lice management which may be required as a result of these changes.
Any available information about the socio economic impacts of implementing the new EQS

Response and reaction to the consultation

We received 25 consultation responses: The responses came from the following groups:

Respondent Group	Number	CS/Email
Marine Finfish Farm Operators/Developers	5	3 Citizen Space / 2 Email
Trade Bodies	2	2 Email
Fisheries Interest	1	1 Citizen Space
Community Groups	2	1 Citizen Space / 1 Email
Environmental NGOs	3	3 Citizen Space
Public Bodies	1	1 Citizen Space
Others (i.e. Individuals)	11	12 Citizen Space / 1 duplicate

The responses to the consultation were highly polarised. Respondents from community groups, NGOs and respondents included in the 'others' group, were particularly focused on the following key points:

Overall, the majority of responses supported the underlying principle of reducing the threshold for discharging quantities of emamectin benzoate into the marine environment and the adjustment of fish farm practices to meet new environmental limits.

Most respondents commented that the new EQS should be implemented immediately since its review was initiated in 2016.

Some stated that consideration could be given to implementing the new EQS in a phased approach to allow for business to make necessary adaptations prior to any action to reduce discharge limits at existing farms.

Whilst many respondents suggested that there is already a strong and demonstrable negative impact from discharging emamectin benzoate from fish farms to the environment, only a few of the aforementioned groups provided evidence in support of this view.

However, most of the respondents who supported the revised EQS did not provide a response to the second and third questions. A few responded that the questions were not relevant to their interests.

Most responses from fish farm operators and trade bodies, raised concerns, mainly around the impact of the threshold to the aquaculture business. Whilst some fish farm operators indicated a minimum timescale for the implementation of the new EQS, their response was caveated, requesting that no implementation occurs until a wider review of setting the EQS take place. They were particularly focused on the following areas:

Several/most respondents questioned the justification for the new EQS threshold, requesting its implementation be put on hold until further scientific evidence is produced demonstrating the requirement to protect the environment.

Further, some stakeholders stated that there was no evidence or not enough evidence to suggest that there is an impact on the environment from the discharge of emamectin benzoate from fish farms.

Stakeholders also raised concerns around the timing of the proposed EQS, and its proportionality specifically in terms of the potential impact this will have on the fish farm industry to supported farmed fish health and welfare, including whilst work to progress the regulatory review of aquaculture consenting and development of SEPA's sea lice risk assessment framework are ongoing.

Most industry stakeholders requested that no implementation occurs until a wider review of access to medicines and the controls on their use has been conducted.

Not all responses followed the format of consultation questions and so direct and numerical comparison between question responses was not always possible or useful. Instead, Scottish Government has used a qualitative approach to analyse the consultation responses by collating them into recurring themes. The descriptors (e.g. few, some) used when describing the recurring themes reflect the number of responses submitted that mentioned, commented, discussed, or answered a direct question from the consultation hub, relating to that theme.

Table 1 shows a table that correlates the descriptors and the corresponding number of responses.

A few	<%	1 - 2
Some	up to %	2 - 4
Numerous/Several/Multiple	% to %	4 - 8
Most	% to 100%	8 - 12

These themes and comments are briefly summarised below.

Question 1: Appropriate timescales for the implementation of the new EmBz EQS.

Option	Total	Percent
0 months	12	52.00%
24 months	0	0.00%
48 months	0	0.00%
Other	6	20.00%
Not Answered	7	28.00%

Most consultees, primarily from individuals, NGOs and community groups, indicated that the threshold should be implemented immediately. A few responses stated that there was substantial evidence of the harm done to the environment from fish farm discharges and that sufficient time had passed from the start of the review to allow time for the industry to adapt.

Some responses included in the 'others' group indicated that a phased-in approach could be considered and indicated that 12 months should be sufficient to account for industry's adaptation.

A few responses from NGO's and community groups indicated that two production cycles (48 month period) is sufficient for the introduction of the new EQS.

A few responses from the fish farming sector indicated that if the new threshold was implemented, the industry would require a minimum of 5 to 6 years prior to implementation to allow for a degree of adaptation.

No respondents provided specific evidence to underpin their answer to this question. However, in their commentary most fish farm respondents raised the following themes. No commentary was provided by non-industry respondents.

Justification for the implementation of the new emamectin benzoate EQS

There were several responses that challenged the justification for the implementation of the new EQS. Most of these responses came from marine fish farm operators and trade bodies. Specifically, the comments questioning the need for the new EQS.

Concerns about the regulatory approach and proportionality of the regime

A few of the responses raised concerns about the proposed implementation of the EQS and more particularly, its suitability as a regulatory control for the activities of marine fish farms. Most representations from the marine fish farm operators and trade bodies expressed concerns that the proposals would create controls that would be disproportionate to the environmental risks and would therefore constrain, unnecessarily, development or even create a moratorium.

One of the key concerns expressed by marine fish farm operators, and trade bodies respondents was that the regime would not be proportionate to the scale of risk. This was linked to specific scientific questions but also to industry's belief that SG and SEPA should consider a regulatory approach that recognises the environmental differences in marine and transitional waters.

Challenge to Underpinning Science

In general, those fish farm operators who responded believed there is insufficient scientific evidence of emamectin benzoate discharge from fish farms having a significant impact on wild crustaceans in Scotland to warrant the introduction of the proposed new EQS. Whilst, there was a recognition from some in the sector that regulation of marine fish farms should encompass discharging limits, they believed that the proposed approach went beyond the evidence and would be overly precautionary.

Scottish Government response

This consultation sought opinion on the implementation timescales of the scientific recommendations made by UKTAG for a new EQS for emamectin benzoate in order to take account of any wider implications of the new threshold for fish farm operators. Standard protocol is for the Scottish Government to adopt UKTAG recommendations and therefore this consultation as focussed on the implementation timetable.

We use EQSs to control the risk to the ecological quality of Scotland's water environment, to protect and improve water quality and to ensure waters achieve or return to Good Environmental Status.

The setting of an EQS is focussed on establishing a safe level of use of a pollutant such that there is no adverse impact on the environment. Any change to an EQS for reasons beyond that of the scientific evidence has the potential to undermine environmental protection more widely. By controlling the quantities of medicines that can be administered, we limit medicine discharges to levels calculated not to breach environmental standards. It is important that the environmental standards we use are based on the best scientific evidence available.

Responses from industry are suggesting that thought be given to deriving different EQS for different situations and marine environments to take into account dispersion. The UKTAG EQS derivation process is based on consideration of available toxicity data. However, SEPA already use dispersion models in their exposure assessment. They use their site models to model dispersion of emamectin benzoate after its use, and from that calculate how much emamectin benzoate can be used at each fish farm to treat fish such that the EQS will not be breached.

Q2 - Please provide any evidence on how long it might take to implement any adjustment to sea lice management which may be required as a result of these changes.

Fish farmers use a range of tools to control sea lice. Their preferred option is the use of emamectin benzoate as an in-feed medicine as it is easy to administer and does not require fish to be crowded or handled, therefore avoiding physical damage, stress or increased mortality in comparison to bath or physical treatments.

Most consultees, including those from fish farm operators and trade bodies, were unable to provide specific evidence on how long it might take to implement any adjustment to sea lice management as a result of the change. However, all industry responses focused on the operators ability to control sea lice effectively, the long-term health and welfare of farmed fish and its potential to impact business.

The sector is concerned that the application of the new standard is likely to reduce the number of treatments that can be made in a cycle, and therefore limit their ability for interventions on fish that would otherwise be considered too small to handle. It is widely accepted that this will likely result in poorer outcomes for farmed fish health and welfare and has the potential to impact business.

Scottish Governments Response

Scottish Government acknowledges that the application of the new EQS is likely to reduce the number of treatments that can be made in a cycle. Emamectin benzoate is persistent in the environment, breaking down slowly, therefore, to avoid exceeding the environmental standard, sufficient break down is necessary before more can be accommodated or increased waste capture is required.

A change on the permitted pattern of use of emamectin benzoate is one of the areas which the Farmed Fish Health Framework (FFHF) is already exploring, in order to achieve better control earlier in the production phase and avoid parasite resistance.

Q3 - Where appropriate, please provide any available information about the socio-economic impacts of implementing the new emamectin benzoate EQS.

The majority of the consultees were unable to provide an accurate response about the socio-economic impacts that may occur from the implementation of the revised environmental standards set out in our recent consultation.

A few responses however, primarily from NGOs and community groups, stated that there was substantial evidence of the long term harm to the environment asserting that the degradation of ecosystems due to excessive discharges from fish farms can have both direct and indirect socio-economic impacts.

Scottish Governments Response

Uncertainty around the socioeconomic impacts of the new EQS threshold features in most responses from industry as well as from other groups. All respondents made assertions of an anecdotal nature that are difficult to verify.

Conclusion and Next Steps

The River Basin Management Planning process, underpinned by the Water Environment and Water Services (Scotland) Act 2003 (WEWS) and the Water Environment (Controlled Activities) (Scotland) Regulations 2011 (CAR), is the key mechanism that identifies and delivers improvements to the water environment that are technically feasible and proportionate to make. This allows us to strike the right balance between protecting the water environment and securing its sustainable use for the purposes of economic and social development.

CAR requires SEPA to control activities which can have adverse effects on the water environment, such as discharges, abstractions, impoundments and engineering works in the freshwater environment.

SEPA uses its regulatory powers to:

protect the water environment and prevent deterioration of status;
ensure improvements are made to status of the water environment;
safeguard an appropriate level of environmental capacity for future sustainable development; and
protect the social and economic interests of other users of the water environment.

The majority of environmental and non-industry interest has been broadly supportive of the immediate implementation of the new EQS with a few expressing concern that the EQS does not go far enough, asserting that Scottish Government and SEPA may take too long to take action.

Significant concerns were raised by the fish farm industry regarding sea lice treatment options particularly at the early stage of the salmon life cycle resulting from the implementation of the new EQS threshold for emamectin benzoate. The industry is also concerned about the limited alternative medicinal options for sea lice management, and the uncertainty around the socio-economic impacts that the introduction of the new threshold may bring.

Scottish Government acknowledges that the application of the new EQS is likely to reduce the number of sea lice treatments that can be made in a fish farm production cycle. We recognise concerns about maintaining fish health, whilst also recognising our obligation to protect the environment. For this reason, Scottish Government intends to direct SEPA to apply the new EQS in 48 months' time, the maximum transition timeframe consulted upon.

This will also allow industry to gain information and better understand socio-economic impacts. It also allows SEPA's to work with the fish farm industry to enable it to identify a timetable for making the improvements that are reasonable and proportionate. Among other things, this includes enabling operators to plan any necessary investments needed to make the improvements or mitigate the effects on

their operations of doing so. Emamectin benzoate is persistent in the environment, breaking down slowly, therefore, to avoid exceeding the environmental standard, sufficient break down is necessary before more can be accommodated.

SEPA will work with the operators of fish farms to ensure they have the information they need on the reduction in their licenced discharge limits that will be required so that they can plan accordingly. As part of its adaptive approach, SEPA have been reviewing whether there might be an alternative simpler method to calculate the volume of emamectin benzoate available to a site dependant on the EQS applied.

On the basis that all sites with a license to use emamectin benzoate have been modelled and previously subjected to a detailed assessment as part of setting the original limits, SEPA are content that using direct scaling of the output from the model against the new recommended standard would be appropriate to amend the relevant authorised volumes.

Scottish Government intends to introduce the new EQS by means of a Direction to SEPA. The EQS will be used to support the Water Environment (Controlled Activities) (Scotland) Regulations 2011 licencing process. When the Direction is in place, SEPA will confirm emamectin benzoate (EmBz) volumes that will be authorised under the new EQS for each site and share them with the relevant permit holders.

Due to the persistence of emamectin benzoate in the environment, particularly in marine sediments, it is likely to take some time before concentrations resulting from previous discharges decline sufficiently to achieve the new EQS.

It is standard practice for SEPA to avoid short introduction periods for significant changes in standards and regulations. As individual fish farm sites will be at different stages of their production cycle, 48 months is likely to be the best fit with planning and investment horizons across multiple operators. Likewise, the 48 months' timescale provides SEPA with sufficient time to implement the change in each fish farm license individually.

We expect SEPA to take this into account in planning how operators of marine fish farms demonstrate progress in delivering environmental improvement. The time of the implementation however, must not exceed the 48 months' limit that SG will set by means of Directions to SEPA. Within the 48 months' window, we expect SEPA to work with the sector to identify the most efficient method to vary permits to ensure they are varied by the date set out in any direction. Those variations will restrict operators to volumes based on the 272ng/kg dry weight standard and will be issued on a zero-base basis (e.g. not taking account of previous treatments carried out under the 763ng/kg framework).

The new variations will also include enhanced additional monitoring requirements (as introduced in SEPA's 2019 framework) to allow for a more detailed understanding of the impact in the environment.

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Any enquiries regarding this publication should be sent to us at

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