| SEPA POSITION STATEMENT TO SUPPORT THE IMPLEMENTATION OF THE WATER ENVIRONMENT (CONTROLLED ACTIVITIES) (SCOTLAND) REGULATIONS 2011 | |
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# WAT-PS-17-03: INTERIM POSITION STATEMENT FOR PROTECTING THE WATER ENVIRONMENT UNTIL SUCH TIME AS A DIRECTION IS ISSUED ON AN EQS IN RELATION TO EMAMECTIN BENZOATE IN FINFISH FARM REGULATION

THIS DOCUMENT OUTLINES SEPA'S POSITION ON FINFISH FARMING ACTIVITIES AND PROVIDES A BASIS FOR INTERPRETING SEPA'S OBJECTIVES UNDER THE CONTROLLED ACTIVITY REGULATIONS (CAR)

| Date | Jan 2021 | Version | 3 |
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## 1 PURPOSE

This statement sets out our interim position on the environmental standards that we will apply when assessing applications to discharge the in-feed sea lice medicine, emamectin benzoate, into the marine environment pending the establishment of new environmental standards for the medicine.

The interim regulatory position and regulatory guidance are unchanged from the version published in December 2019. This version includes updates to the supporting guidance included at the end of the Statement.

## 2 BACKGROUND

We use environmental standards to protect the marine environment from discharges of medicines from fish farms. By controlling the quantities of medicines that can be administered, we limit medicine discharges to levels calculated not to breach the environmental standards.

It is important that the environmental standards we use are based on the best scientific evidence available. As evidence changes, the standards may need to be updated accordingly.

In 2016, we commissioned independent scientific work to review the existing environmental standard for emamectin benzoate, the active ingredient in the sea lice medicines marketed as Slice and Quinafish. The review was prompted by indications from a study by the Scottish Association for Marine Science that the use of the medicine may be affecting crustaceans, a large and diverse group of animals that include shrimps, lobsters and crabs. It was undertaken by the consultancy, WRc and completed in 2017. It recommended new, tighter environmental standards for emamectin benzoate.

Following the conclusion of the WRc work, in our interim position statement issued in October 2017, we set out our regulatory approach pending the establishment of new environmental standards for the medicine. Under that interim position, we have been applying the standards recommended by WRc to assess and control the risk posed to marine protected areas and priority marine features from proposed new or increased discharges of emamectin benzoate.

In 2017, we conducted a survey of waters around fish farms to trial improved environmental monitoring strategies. Our subsequent analysis during 2018 of the environmental samples collected identified evidence of impacts on crustaceans. The impacts were proportional to the concentrations of emamectin benzoate in the seabed and were present at concentrations of the medicine below the current environmental standard. We have provided these findings to UKTAG.

The results of the analysis have increased the now substantial weight of scientific evidence that the existing standards do not adequately protect marine life. In light of this, and pending the establishment of the new standards, we are replacing the October 2017 interim position with this new, revised interim position. The revised position extends our use of the standards proposed by WRc to include assessing and controlling the risk posed by proposed new or increased discharges of emamectin benzoate to any areas of coastal waters.

In parallel, we progressed work to establish new environmental standards: We invited the sector and the medicine manufacturer to provide any additional scientific information that they may have on the toxicity of emamectin benzoate. We then requested the UK Technical Advisory Group (UKTAG) to consider all the available scientific evidence and make recommendations to Scottish Government on new standards. UKTAG is a partnership of the UK's environment and conservation agencies. It was set up jointly by the different government administrations from across the UK to provide scientific advice on environmental standards and other matters relating to the protection of the water environment.

In November 2019 UKTAG published the responses to its consultation on the proposed environmental quality standards for emamectin benzoate. In this document, UKTAG has advised, that additional information has been supplied and this data will be included in a further review and as such no standard is being recommended at this time. However, UKTAG did indicate in the response that the evidence did not support a standard which was lower than that proposed in their consultation (23.5 ng/kg dry weight of sediment). After UKTAG makes its recommendations to the Scottish Government, Scottish Government will consult on draft directions on establishment of the standards.

## 3 INTERIM REGULATORY POSITION

**A. Interim position for the determination of applications for new licences or variations to existing licences where new or increased discharges of emamectin benzoate are proposed**

When determining the above applications, the applicable environmental standards will be as follows:

| **Interim environmental standards** | |
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| Cage edge<br>(i.e. sea bed directly beneath the cage edge) | 235 ng per kg of marine sediment<br>(dry weight) |
| Mixing zone edge<br>(i.e. sea bed at 100 metres from the cage) | 23.5 ng per kg of marine sediment<br>(dry weight) |

We will limit the total quantity of emamectin benzoate that can be administered in order to ensure compliance with the above interim environmental standards

**B. Interim position for existing, authorised discharges of emamectin benzoate**

We will continue to ensure previously authorised discharges comply with their conditions of authorisation.

We will work with operators to seek their agreement to a voluntary reduction in the maximum quantity of in-feed treatment permitted for use by 60%.

## 4 REGULATORY GUIDANCE

We will assess whether any proposal of the types listed below would result in concentrations of emamectin benzoate in the marine environment greater than the interim environmental standards. To do this, we will use the modelled data provided by the applicant.

If the modelled data are consistent with the achievement of the interim standards, we will authorise a total allowable quantity (TAQ) in accordance with the output of the model. Where the results are inconsistent with the achievement of the interim standards, we will refuse to authorise use of the quantity of emamectin benzoate being proposed.

**Types of proposal to which we will apply the interim environmental standards**

1. Proposals to use emamectin benzoate at: farms re-locating outwith their current environmental footprint

   a) new farm sites;
   b) farms re-locating outwith their current environmental footprint;
   c) existing farms with no previous authorisation to use emamectin benzoate; and

2. Proposals to increase the use of emamectin benzoate at:

   d) existing farms already authorised to use emamectin benzoate.

**Taking account of new environmental monitoring or modelling information**

Existing farms that we have already authorised to discharge emamectin benzoate under the existing environmental standards rather than the interim environmental standards sometimes apply to vary other parts of their authorisations (e.g. limits on biomass; bath medicine residue discharges; etc.). To support such applications, the farms will often submit new environmental monitoring or modelling information.

Where such new information is submitted, we will use it to check that the quantity of emamectin benzoate the farm is permitted to administer under its authorisation is low enough to ensure compliance with the existing environmental standards. Where it is not, we will vary the authorisation accordingly.

## SUPPORTING GUIDANCE ON APPLICATION OF THE INTERIM POSITION

**1. What is the purpose of interim position statement?**

To set out SEPA's position to avoid risk of deterioration of the water environment (i.e. risk of increased harm) when assessing applications for authorisation to discharge emamectin benzoate pending the establishment of a new environmental standard.

**2. What sort of activities could pose a risk of deterioration? Activities such as:**

- Emamectin benzoate discharges at newly proposed sites.
- First time or increased emamectin benzoate discharges at existing sites.
- Emamectin benzoate discharges at relocated or expanded sites.

**3. What does the interim position mean for proposed new sites?**

You will only be able to obtain authorisation to discharge emamectin benzoate if you can show that the discharge of emamectin benzoate would not breach the interim environmental standards for (a) the cage edge; and (b) the edge of the 100 metre mixing zone.

You will only be able to stock the site with fish that have been previously treated with emamectin benzoate (i.e. before being brought onto the site), if you have authorisation to discharge emamectin benzoate, and can show that the release of emamectin benzoate from those fish would not breach the interim environmental standard for (a) the cage edge; and (b) the edge of the 100 metre mixing zone.

**4. What does the interim position mean for existing sites applying to use emamectin benzoate for the first time?**

You can apply for authorisation to discharge emamectin benzoate and we will apply the requirements described in 3 above for new sites.

**5. What does the interim position mean for existing sites applying to increase their use of emamectin benzoate?**

You will not be granted authorisation for any increased use of emamectin benzoate unless you are able to show that:

- under your current authorisation, you are meeting the interim environmental standard at the edge of your farm's predicted emamectin benzoate footprint; that is the area of seabed over which the interim environmental standard is predicted to be breached; and
- under your proposed revised use of emamectin benzoate the quantity of emamectin benzoate residue predicted to be exported beyond the model grid would not be greater than under your existing conditions of authorisation; and

  the emamectin benzoate footprint is not predicted to increase or affect any new areas of seabed compared to the current predicted footprint.

**6. What does the interim position mean for existing farms proposing to relocate outwith their current environmental footprints?**

If you relocate your farm outwith its environmental footprint, your discharge of emamctin benzoate will be treated as a new discharge for the purpose of this regulatory position (see 3 above). "Re-location" in this context refers to the relative positions of the environmental footprints of your farm before and after changes in farm infrastructure. Your farm will be considered to have re-located outside its environmental footprint where the pens are being moved (or replaced and re-positioned) over:

- such a distance that there would be no overlap between the new environmental footprint and the farm's current environmental footprint; or
- such a distance or in such a way that the degree of non-overlap would be significant or the area of the footprint would be larger (ie because the assimilative capacity at the new position of the pens is lower than at their previous position).

**7. What does the interim position mean for existing sites that have used emamectin benzoate but not applying to make any changes?**

The interim position statement applies to the assessment of applications to discharge emamectin benzoate. Consideration of any actions to take regarding existing sites for which no application has been made will be made on a site-specific basis taking account of the risk of deterioration. We will work with you to identify sites at risk of causing deterioration and review and vary your authorisation as necessary to protect the environment from such a risk.