UK Technical Advisory Group

Proposed Biological and Environmental Standards for River Basin Planning

Consultation Response Report

October 2019

wfd Water Framework Directive UK TAG

CONTENTS

About this document

The UK Technical Advisory Group (UKTAG) has sought views and comments on the scientific work that underpins the latest set of proposals for biological and environmental standards. The standards are designed for use in taking decisions under the Water Framework Directive (WFD). The consultation document was published on the UKTAG's website in May 2019.

UKTAG received 32 responses, raising over 90 comments and questions, from stakeholders across a wide range of sectors including academia, consultancy, energy, engineering, non-governmental organisations, pharmaceuticals, third sector, transport and water. We found the comments received to be very helpful in progressing our understanding of this work and as a result, we have identified:

- Changes that could be made to the proposed standards.
- Issues that need to be addressed, but which do not change our proposals at this time. (for example, explaining better how the standards might be used, expanding on future work, and identifying issues that we cannot currently deal with).
- Issues for the attention of the UK administrations and UK agencies.

A physical copy of this report can be provided upon request.

Status of proposed standards following consultation

UKTAG's recommendations for approval, together with a list of changes and further actions on the proposed standards are set out below. A summary of the feedback received for each standard is provided in the "Summary of Responses" section and full details of all stakeholder comments and our responses can be found in Annex A.

UKTAG has discussed the feedback with the authors of the technical reports that underpin our proposals and with representatives from the UK administrations prior to publication.

River flows	
Recommend standard be approved:	Yes
Changes following consultation:	A recommendation to the UK administrations that the regulation of abstractions should ensure that rapid fluctuations in river level are avoided.
	Clarification of the exemption tests which determine when the short-term abstraction revisions should not be applied.

Invasive non-native species	
Recommend standard be approved:	Yes
Changes following consultation:	Japanese kelp, *Undaria pinnatifida,* has been added to the Ecoregion 17 high impact list in relation to the Invasive Non-native Species list.

Lake nitrogen	
Recommend standard be approved:	Yes
Changes following consultation:	None

River fish classification	
Recommend standard be approved:	Yes
Changes following consultation:	None

Emamectin benzoate Environmental Quality Standard (EQS)	
Recommend standard be approved:	No
Changes following consultation:	We have been informed of three additional long-term sediment toxicity studies in the responses received. UKTAG will follow up on the new data and information as it may be significant in terms of the derivation of a sediment EQS and it will be considered alongside all the other comments and responses provided. Currently we are not aware of any other laboratory studies or other quantified field evidence that supports a more precautionary standard than that which we proposed. We expect the process of reviewing new information to take some time.
	We will seek access to the study reports/ study summaries to review their suitability for use in the derivation of an EQS.
	We will conduct further review of the two available field studies through an external independent third party.
	We will consider further the protection of the marine environment and marine activities' regulation, in relation to the protection goals that exist for River Basin Specific Pollutants.
	We will produce a revised EQS proposal based on consideration of the above and consideration of the comments received. This will be subject to independent peer review, either in full or targeted to its critical elements.

Summary of responses

This section summarises the main issues raised by stakeholders. Details of each response are shown in Annex A.

General comments

Several responses related to the potential implementation of standards in one or more countries of the UK. UKTAG is unable to answer these questions as it is not a policy making body and cannot provide assessment or comment on how standards may be used within each country's policy framework. Instead, we recommend such comments be made to the environment agency of the country of interest during the appropriate consultation phase of their river basin plan.

There were reminders that the implementation of standards proposed to help achieve the Water Framework Directive need to consider the timetable for investment planning undertaken by the water industry.

Many respondents welcomed the review of standards proposed by UKTAG and the inclusion of lake nitrogen as a new standard for the UK.

The importance of endocrine disrupting chemicals in assessing the WFD status of a river was also raised. UKTAG will consider the need for new standards separately from this consultation as part of its usual processes for new chemical standards.

Summary for Chapter 2: River flows standards

We received responses from twelve organisations on the proposed revisions to the river flow standards. These responses represented stakeholders from businesses in the water sector, recreation, farming and UK government bodies.

The majority of responses were supportive of the proposed changes and were satisfied that UKTAG had followed the appropriate EU guidance when making these proposals.

Several questions were raised regarding the changes to the high status standard to take account of elevated flows. One question related to the evidence itself, querying whether the impacts seen might have been due to water quality impacts. UKTAG is satisfied that such confounding effects have been addressed in the research methodology as far as is practical.

Another set of questions related to the implications that these proposals for changes in high status may have for the other ecological status classes and, consequently, whether the proposals might trigger revisions of existing authorisations that currently allow elevated flows. We would point out that such revisions apply to high status only and other determinations should take into account ecological evidence. As to whether these may result in changes to

existing authorisations, this is a matter for the relevant UK administrations. The provisions of the WFD are such that the cost implications for implementing measures in achieving water body objectives should be taken into account.

For the proposal to introduce a method to account for short-term abstractions within the river flow standards, eleven responses supported the proposal and one objected to it. The response objecting to the proposal indicated that the evidence did not support this revision and, in particular, raised the concern that rapid fluctuations in river levels would risk stranding fish. The proposals here address the gap in the existing standards, evidenced in the literature review, which currently do not consider the duration of abstraction as a determinant of ecological harm. UKTAG does recognise the risk to fish of rapid level fluctuation as presented in the evidence underpinning these revisions but notes that this is a matter of implementation, which may relate to matters wider than this proposal. As such, the UKTAG recommends that this potential impact should be considered as part of the regulatory processes in licence assessment and determination within the devolved administrations.

Summary for Chapter 3: Invasive Non-Native Species list

We received five responses specific to INNS. Two responses expressed overall support of the approach taken by UKTAG, the other three responses related to specific species listings.

One respondent questioned the evidence for the listing of *Crassostrea gigas* (Pacific oyster). This species listing has not changed since the last standards consultation. UKTAG base the listing of species on the independent and peer reviewed risk assessments for both the island of Ireland (Ecoregion 17) and Great Britain (GB).

The second specific response related not to the listing of a plant (*Gunnera* spp.) itself, but to potential issues with management measures, particularly relating to the sale of species. Management measures are not part of the standards consultation as we base the listings of species on their ecological risk. We hope that alongside other legislation, such as the EU Invasive Alien Species Regulation, the listing of species on the high impact lists will drive appropriate management measures. We have listed the two species under the generic *Gunnera* spp. to accommodate the difficulty in taxonomically separating them.

A final response from Northern Ireland Environment Agency (NIEA), on behalf of Ecoregion 17 Alien Species Group, raised the potential addition of two species to the Ecoregion 17 list: firstly, the freshwater yabby, *Cherax destructor* following the discovery of a population in Ireland and secondly Japanese kelp, *Undaria pinnatifida*. The UKTAG Alien Species Group have discussed the new population of *Cherax destructor* and agree that it should not be added to the list at this time, given that it is believed to be a single discrete population and not considered to be established in Ecoregion 17. We will add *Cherax destructor* to the Ecoregion 17 alarm list. We will add *Undaria pinnatifida* to the high impact list for Ecoregion 17 based on expert judgement and information from the GB risk assessment.

Summary for Chapter 4: Lake Nitrogen standards

Responses were received from nine organisations, with seven of these providing some detailed comments. The majority of respondents supported the proposal to introduce nitrogen standards for lakes, to be assessed as an independent supporting element (Questions 5 and 6 in the consultation report), but the method used to derive the standards and the supporting evidence base were not considered adequate by some respondents (Question 7).

UKTAG has considered the responses carefully, and we have provided detailed comments in Annex A. A number of the comments received did not relate to the derivation and application of the standards themselves, but rather to the implications for subsequent identification of measures, and the likely cost and effectiveness of these. In particular there was concern that investment to reduce nitrogen concentrations may have little effect in lakes where phosphorus was the limiting nutrient.

One response received suggested that the derivation of standards had not taken account of observed biology, however we consider that the method described in detail in Annex C to the report is based on the relationship of nitrogen to phytoplankton and follows the guidance on standard derivation published by the WFD CIS Working Group ECOSTAT.

Another response was not supportive of the use of total nitrogen as the parameter for the standard, suggesting soluble nitrogen species would be more appropriate. UKTAG has considered the use of alternative determinands, but has concluded that in lakes total nitrogen reflects the nutrient load to the system in the same way that total phosphorus is used for the lake phosphorus standards. The use of total nitrogen for the standard does not preclude more detailed investigation of the nutrient dynamics of individual water bodies involving assessment of the soluble nitrogen component if required.

Two respondents felt that the standards should not apply to heavily modified or artificial water bodies used primarily as storage for water supply. UKTAG has considered this matter carefully, we believe that standards for supporting physico-chemical elements (including one or more nutrients) should apply to these lake water bodies, particularly in relation to phytoplankton status, as phytoplankton are not considered to be impacted by the use of the water body. However decisions on the suitability and use of the proposed nitrogen standards, alongside existing phosphorus standards, in specific circumstances, are a matter for the UK Administrations and their agencies to consider at a country level.

In terms of the concentrations of total nitrogen proposed for the class boundaries, there was no disagreement with the standards (boundary values) for high, good and moderate ecological status. Some concern was expressed that the setting of boundary values for poor and bad status had not been based on a direct relationship with ecological status but on a doubling of the values from the moderate/poor boundary. This approach follows the precedent set by, and is therefore consistent with, the total phosphorus standards in lakes. UKTAG accepts that this approach is not ideal, but we believe it is a pragmatic way of providing management targets by which improvement towards better status can be measured. Classifications of supporting elements below moderate status do not influence the formally reported water body classifications.

While we note the concerns raised, UKTAG believes that there is sufficient scientific evidence for the impact of nitrogen in lakes to justify the proposed nitrogen standards. The approach to implementation of standards and measures to address any failure to meet good status is a matter for individual UK agencies, but as stated in the consultation report UKTAG expects this would be assessed as part of a wider "weight of evidence" review considering the impact of eutrophication, the most likely limiting nutrient (nitrogen and/or phosphorus) and the most effective control measures, which would themselves be subject to a cost-benefit review.

UKTAG will work to provide further technical guidance to assist the UK agencies with lake nutrient investigations following classification, in particular on the identification of whether nitrogen or phosphorus, or in some cases both nutrients, need to be controlled in order to improve ecological status.

Summary for Chapter 5: River fish classification (Scotland)

The main issues raised were in relation to the combination of site data to produce a water body classification and the impact of this on the One-Out-All-Out principle. Our proposals do not affect the One-Out-All-Out principle applied at the water body scale. Instead, the proposal modifies how site data is combined within a water body to produce a more accurate classification of the fish communities in response to the pressures that affect them.

A separate question was raised about the implications of these changes for the Controlled Activity Regulations in Scotland in relation to compliance assessments. We believe that the revised approach provides a more accurate assessment of the environment and these issues should be addressed through direct liaison with the devolved administration.

Summary for Chapter 6: Emamectin benzoate EQS

Thirteen responses were received on the proposal for a revised environmental quality standard (EQS). UKTAG asked two questions in relation to this standard; question 9 asked if stakeholders support the derivation of the proposed EQS and question 10 asked whether there is any other relevant data that has not been considered in the derivation of the EQS.

Of the responses received one fully agreed with the derivations and resulting EQS values. Other responses identified reasons why, out of the three EQS presented, they believed revision to the proposals for the water Maximum Acceptable Concentration (MAC) EQS and sediment EQS were required. Some respondents believed the proposal to be too stringent, others too permissive. Reasons for these views included: the choice of assessment factors used in the derivations; whether assessment factors used to derive the MAC were sufficiently protective of all aquatic species, including larval stages of commercially important species; the use of freshwater insect data in setting marine standards; and possible differences in sensitivities between marine and freshwater organisms (in relation to the proposed sediment standard).

One response provided results of three additional long-term sediment toxicity studies. For one of these studies, a short summary report was also provided. These new data and information are potentially significant in terms of the derivation of a sediment EQS and will be considered alongside all the other comments and responses provided. We have not received any data in support of a more precautionary standard than the original recommendation from UKTAG of 23.5 ng/l.

We have summarised the remaining responses under appropriate headings. Full details of the comments received and responses are included in Annex A.

Methodology – selected assessment factors

We received a number of comments on the assessment factors used in setting the pelagic MAC EQS and the sediment EQS. For the MAC EQS, we will reconsider the dataset alongside the comments raised re: protection of all aquatic species including larval stages of commercially important species and the assessment factor used. For the sediment EQS, we were made aware of significant new data. We will ask for study reports or robust study summaries to be made available so that we can review this additional data, which may lead to a revised EQS proposal including a change to the assessment factor applied.

Data Interpretation – use of *Arenicola* data (in sediment EQS)

We received a number of comments which are supportive of not using the sub-lethal endpoint from the acute *Arenicola* study in the derivation of the sediment EQS. Some responses also commented on the lack of a chronic study for this species and its relative sensitivity. A new study has been conducted for a ragworm species (one of the three referred to above). As part of our review of the new submitted data (assuming it is made available), we will consider its relevance to *Arenicola*.

Data interpretation – use of insect data (in sediment EQS setting)

We received a large number of detailed comments on the use of freshwater insect data in setting a marine EQS. The majority of these were not supportive because they believed insect species are less relevant for the marine environment being fairly rare and found only in intertidal zones. In addition, to date, the industry that uses the substance as the active ingredient in a veterinary medicine has been regulated only through surveys of impacts on sub-tidal benthic communities. In considering the comments received, we will seek further expert advice on the use of such species in the protection the marine environment. We will also seek policy advice on what the EQS for this substance is trying to achieve in relation to the protection goals of a marine EQS for a specific pollutant (which include all areas within the marine environment from transitional and coastal waters up to three nautical miles off shore).

Data Interpretation – comparing fresh and marine water datasets; mode of action and statistical factors

We received a number of detailed comments on differences in sensitivities of fresh- and marine organisms to the chemical's mode of action, as well as a statistical demonstration including the three new sediment studies that the difference between the fresh and marine sediment datasets toxicities was statistically significant. The former will be considered as part of the work noted above to consider the use of a freshwater insect to derive a marine EQS. In terms of assessing whether the fresh and marine data are statistically different, we will look

further at the complete datasets, including the new study data. Further comments on this aspect are included in the annex's technical comments.

Data Interpretation – field studies

We received conflicting comments on the use of the field data in this derivation. The majority disputed the findings of the SEPA study, with one submission having apparently conducted reanalysis of the data. We will reconsider the two available field studies taking into consideration the comments received. This may include letting a contract to a third party to reanalyse all the data, provided all the required study details are made available to us.

New ecotoxicity test data

Several respondents referred to additional studies being available on the toxicity of emamectin benzoate to aquatic organisms. SSPO provided further detail on these additional data, which comprise:

1. Chronic 28-day growth study for the ragworm *Hediste diversicolor*;
2. Life cycle toxicity study for the sediment-dwelling midge *Chironomus dilutus*;
3. Life cycle toxicity for the amphipod *Hyalella azteca*.

We have requested further details of these studies so that we can verify their reliability for use in the derivation of the sediment EQS. These data greatly extend the available database for sediment toxicity and will be invaluable in the derivation.

Further to the comments received during the consultation, we will take the following actions:

- Request access to study reports or robust study summaries of the three new chronic toxicity tests in sediment dwelling organisms, and review their suitability for use in the derivation of an EQS for emamectin benzoate.
- Conduct further review of the two available field studies through an external independent third party.
- Consider further the protection of the marine environment and marine activities' regulation, in relation to the protection goals that exist for River Basin Specific Pollutants.
- Produce a revised EQS proposal based on consideration of the new studies, the further analysis of the field data and consideration of the comments received. This will be subject to independent peer review, either in full or targeted to its critical elements and reflective of comments received during the consultation.
- Forward our final recommendation to UK Administrations.
- As part of this process we will, as far as possible, make available relevant data.

Completion of the work outlined above is unlikely to be achievable before summer 2020 due to the number of steps and the need to involve external experts and organisations.

The proposed EQS will not be finalised until all relevant work identified above has been undertaken.

Annex A: Detailed Comments

The complete set of comments received from stakeholders are set out below and organised by chapter. We have reviewed all feedback and provided responses which are intended to:

- Explain our position to the points raised by stakeholders
- Confirm any amendments we propose to make in the final report and relevant supporting documents.

Non chapter-specific comments

Respondent	Question No.	Remark	UKTAG Response
David Nattress	General	I am an angler, secretary of a local fishing club. My members fish on the Afon Eastern Cleddau in Pembrokeshire. I have not consulted with my members on the content of this e-mail. Over the past few years the numbers of fish in our river has declined, markedly. Salmon and sea trout have virtually disappeared, even the stock of brown trout appears to be failing. I appreciate that there are a number of possible reasons for this: diffuse and gross pollution; water temperatures; invasive, non-native, fish eating birds; the effect of water pH and General aluminium on migratory fish; coastal netting; to list the major ones. One which is neglected is the presence of endocrine disrupting chemicals. In the case of our river there are a number of sources – waste water treatment plants, pollution from the dairy industry and its method	As part of our standard approach, any chemicals that might be a risk due to exposure via the water environment, including endocrine disrupters, can be considered for the derivation of EQS. We will continue to keep such risks under review.

		of disposing of waste (there are probably more cows than people in the watershed of the Eastern Cleddau and, over and above what cows naturally produce, they produce even more EDCs when fed on feeds derived from maize and soya beans), innumerable septic tank drainage systems in an area with thin top soils and impermeable bedrock and occasional flushes of cyanobacteria from one of the reservoirs in the system. The effect these must be having on the fish population may be the reason why even minnows are becoming rare in our river. How NRW can possibly describe it as being in an over-all 'good' condition baffles me, but then, as it is a Drinking Water Protected area they may have political reasons for doing so. There would appear to be a case to be made for including endocrine disrupting chemicals as a pollutant of note in assessing the WFD status of a river as they will have an effect not only on the fish but also on any local populations of resident animals, e.g. king fishers and otters if they haven't quit the area for lack of food. I haven't eaten fish from the Eastern Cleddau for years and only hope that the treatment of my drinking water is effective in removing the many pollutants!	
Northumberland Inshore Fisheries and Conservation Authority		Thank you for the correspondence regarding the above consultation. At this stage, Northumberland IFCA has no comments to make however we would be grateful to be kept informed on the progress of the consultation and any outcomes from it.	Noted.

Chapter 2: River Flows

Respondent	Question No.	Remark	UKTAG Response
Stantec	1	In our work for several UK water companies we have also found that flows that are greater than naturalised do not necessarily result in Good or High status. However, our analysis has indicated that this is largely due to water quality issues associated with the discharges that are causing the increased flows. I would therefore suggest that it would be appropriate to consider the type of discharge that is causing the surplus flow before making these changes. If the discharge is treated sewage effluent there may still be some water quality issues that are the cause of the deterioration, whereas if the water discharged is essentially 'natural' water, then the issues may not occur or occur to a much lesser extent. The analysis presented in the consultation does not appear to make this distinction.	Data associated with sites where water quality was a known issue, or if they failed WFD standards for dissolved oxygen or ammonia, were removed from the dataset prior to analysis to take account of confounding pressures associated with water quality where possible
Stantec	2	Again, the approach to short term abstractions seems broadly sensible. However, I am concerned that the approach proposed will lead to some confusion unless further guidance is provided. This is because the proposed changes create a transition from existing flow regulation which is largely built around compliance with long term flow statistics (Q95 etc.) to a time series approach and the exact mechanism for making this transition does not seem to be clear to me in the consultation. i.e. Table 2.2 needs to be explicit about what period is used to calculate the revised flow	The standards relate to the same long-term flow duration statistics as used for the existing standards. The existing standards indicate allowable takes based upon flows on the day and there is no change here. The only difference is that the proposed changes set out the criteria within which a short and infrequent exceedance of a particular proportion of the long-term flow percentile might not result in a downgrade in classification status. The abstractions that the short-term standards apply to primarily occur at times of low flows (irrigation;

		percentiles and hence status (percentiles calculated over shorter periods are more likely to be affected by the event: if long term percentiles are used then even a quite signi9fcant short term event may not affect the percentile much). Intuitively it would also seem to me that a failure to meet the required flow standard during a low flow period would have more significant environmental effects than for a medium/high flow period. However, the method proposed in Table 2.2 would apply equally to events in different flow percentiles and possibly events occurring over a mixture of flow conditions in different years. I would suggest that it may be appropriate to have different tables for high, medium and low flow conditions.	emergency water supply). As such, the standards are designed to provide protection at low flows. We agree that they are likely to be more precautionary at higher flows but feel that the likely rare applicability to high and medium flows does not warrant the complexity of different tables.
Environment Agency (Integrated Environment Planning team, Cumbria and Lancashire Area)	General	I have read the proposed changes to the flow guidance and note that the proposal for applying a temporal element to the flow standard only appears to apply to abstraction and therefore a reduction in flows. My question is would this would also apply to the standard regarding artificially increased flows? This might be the implication but it was not clear to me upon reading it. I think that the proposals sound sensible given the evidence but I wonder if there is a need to be cautious given that the evidence to support these changes is based on macro-invertebrates and not fish and the effects might well differ in terms of recovery times and effects. I fully realise that obtaining evidence from fish populations on such impacts would be very difficult.	• The short-term abstraction exceedances do not apply to augmented flows as the evidence on short term events did not consider artificially elevated flows. However, we have pointed out in the document that the augmented flows standard applies to persistent artificially increased flows only. • Regarding your comment on short term abstraction, the UKTAG expects that the temporal impact matrix should be applied in a precautionary manner. If the data does not provide a high confidence in the temporal variability of abstractions a precautionary approach should be taken in deciding whether the provisions of the short term abstraction proposal are applied. UKTAG will make this clear in the revised recommendations • The evidence suggests that some species, particularly fish, may not be resilient to large impacts that may compromise the connectivity of wetted channel

			habitat. To take this into account the temporal matrix does not apply to large magnitude abstractions that currently breach the poor status threshold. The UKTAG is satisfied with the evidence that fish are resilient to the extent of the scale and duration of impacts that these proposal would allow.
Warwickshire County Council (Flood Risk Management)	1	Agree - No comment.	
Warwickshire County Council (Flood Risk Management)	2	We would welcome this approach in River Basin Management Plans.	Noted.
Warwickshire County Council (Flood Risk Management)	3	Agree - No comment.	
Ulster Angling Federation	1	Agree - No comment.	
Ulster Angling Federation	2	We do not support the proposals to take account of short-term abstraction in classification. We feel the basis for the examination of the effects of short-term abstraction is entirely flawed. Proposal Document Clause 2.20. This states that;	Response to comments on clause 2.20: The initial river flow standards developed by UKTAG in 2008 were formulated based on ecological evidence at that time and were designed to offer general hydrological flow conditions to support achievement of objective ecological status. These standards were considered adequate for abstractions that operate for all, or most of

		"River animals and plants have evolved to live under a highly variable flow regime. This includes short-term periods of naturally low flow, which animals and plants are expected to be better adapted to than longer term events." The statement that animals and plants are expected to be better adapted to short-term periods of low flow is entirely unsupported by any evidence, and is a fatuous justification for relaxing abstraction protections for rivers. Naturally low flow in rivers occurs as a result of very gradual reductions in flows from higher values. In great contrast this standard sets out a justification for increased abstractions of short durations, which occur on a step change basis. Annex A to the document quotes as justification reference 7; [7] APEM (2017): Literature review of short-term flow reduction ecological impacts and recovery. Report to SEPA. https://www.sepa.org.uk/media/336665/sepa-literature-review-of-short-termflow-reduction-ecological-impacts-and-recovery.pdf Paragraph 1.1 on page 2 of this document states; "The focus of this study is to investigate whether there is evidence to support similar temporal variation from the current standards recommended by UKTAG. The temporary, intermittent type of abstraction this is pertinent to typically operates for the purposes of irrigation, or emergency water supply, during dry periods	the time. It was broadly recognised by UK technical experts, at the time, that standards might need to be reviewed in line with developing evidence to ensure that they were ecologically relevant. Concerns have been raised as to whether temporary or occasional short-term abstractions should be treated the same as continuous abstraction. A literature review of temporal aspects of short-term low flow impacts in rivers was commissioned (refer to https://www.sepa.org.uk/media/336665/sepa-literature-review-of-short-term-flow-reduction-ecological-impacts-and-recovery.pdf). This review presented evidence that river ecology is generally resistance to short-term infrequent events (subject to a number of principles). As such, it concluded that there is scope for the introduction of a temporal or spatial element within the standards that may allow for short-term or temporary variation without causing significant environmental impacts or impact on rivers meeting their objective status under the Water Framework Directive. It is on this that these proposals are based. Evidence does suggest a risk of fish stranding due to rapid change in level caused by abstraction, a concern raised here. UKTAG does recognise the risk to fish of rapid level fluctuation as presented in the evidence underpinning these revisions but notes that this is a matter of implementation which may relate to matters wider than this proposal (for example new abstractions or existing abstractions that vary over time). As such, the UKTAG recommends that this potential impact should be considered as part of the regulatory processes in licence assessment and determination within the devolved administrations.

		when river flows are naturally low. Thus, the focus of interest is on abstractions at the low flow end of the flow duration curve." (Our highlight) This is very obviously a completely different circumstance from that which occurs naturally. Therefore, the basis of the standards set out are utterly flawed; apples are being used to justify oranges. Proposal Document Clause 2.21. This states that; "Whilst this may lead to increased densities and potentially greater predation the evidence suggests that there is generally no change to the range of species present during these shorter flow impacts." It is significant that this paragraph or omits any reference to quantitative changes as a result of short-term abstraction, particularly in respect of fish which is primarily our interest. The literature review referenced above is quoted as the justification for the statements in this clause. If one examines the script in this literature review it becomes evident that in fact short-term step change abstractions carry significant risks of fish kills, for example the death of sea trout in one instance. Proposal Document Clause 2.22. This uses the flawed basis of the abstraction justification;	Response to comments on clause 2.21 and 2.22: Whilst we do not make specific reference to quantitative changes to the absolute numbers of specific fish species, we do note that the potential for increased predation may impact on this. The literature review did outline evidence that the short-term nature of the events under review are, in general, unlikely to result in obstructing upstream passage for long enough periods to result in the reproductive physiological window being exceeded. The reference to an anecdotal case of sea trout kill during a late summer irrigation does indeed highlight the requirement for consideration of the timing of proposed short-term abstractions. The devolved administrations will need to consider this when determining an authorisation for a temporary abstraction and setting conditions to mitigate for any potential impact. Regarding the potential for step changes in flow, please refer to our response to 2.20

		"This accounts for the resilience of aquatic ecology to short low flow events but also the need for a recovery period." We would repeat our view that the basis for the examination of the effects of short-term abstraction is entirely flawed. Naturally low flow in rivers occurs as a result of very gradual reductions in flows from higher values. In great contrast this sentence sets out a justification for increased abstractions of short durations, which occur on a step change basis. Proposal Document Clause 2.23. We are astounded that further abstractions are being justified in water flows above Q 98. This means that rivers will only escape further abstractions for seven days per year. In a sense we should not be surprised at this, as so-called protection of rivers under UK TAG recommendations have been largely ineffective. The script states; "However, the likelihood of short-term abstractions occurring, as well as the likely scale of their impact, are greatest at low flows." It defies all logic that ever more escape clauses to Water Framework Directive standards are being introduced. This supports our view that far from protecting our rivers, UK TAG and the relevant environment agencies across	Response to comments on clause 2.23: As stated previously, the river flow standards developed by UKTAG in 2008 were based on ecological evidence at that time and were designed to offer general hydrological flow conditions to support achievement of objective ecological status. UK technical experts recognised at the time that standards might need to be reviewed in line with developing evidence to ensure that they were ecologically relevant. Developments in scientific evidence and experience of the practical application of the standards has driven the need for the standards to be reviewed (in the previous 2012 consultation and for this current review). In this case, differences between the hydrological classification and that resulting from the biological quality elements due to short-term

		the UK have morphed into bodies which mainly exist to protect those who pollute and abstract from our rivers, creating ever more avenues for the avoidance of effective regulation. It begs the question as to why this investigation of abstraction for short durations was ever instigated in the first place. Who called for this, why was it funded, why are more and more ways to damage our rivers being permitted? We would like to propose a completely new radical approach by UK TAG and the relevant environment agencies across the UK. We realise it will require an entirely new experience for these authorities, something which apparently has never been tried before. We suggest that these bodies find ways to protect our rivers, rather than facilitating those engaging in practices which damage them. We have a number of rivers in Northern Ireland where sections of river are regularly abstracted so severely that a dry riverbed, and/or dry weir results. We would like to propose that instead of finding new ways to permit abstractions, UK TAG instigates studies to adequately protect our rivers.	abstractions is why the literature review, which provides the basis for these proposals, was commissioned.
Ulster Angling Federation	3	We feel the proposals for abstractions violate the principle of the WFD to protect our rivers.	These proposals seek to reflect the latest understanding form our evidence regarding the relationship between flow and ecological response to changes in that flow. Ensuring alignment between the scale of impacts indicated by biological and hydrological quality elements

			is consistent with the principles of the Water Framework Directive.
Ulster Angling Federation	8	We disagree with this policy as it is simply a means of relaxing standards. We believe the "one out all out" policy remains the best policy.	The proposals do not alter the 'one out all out' principle, which would still apply.
National Parks Wales	1	Agree - No comment.	
National Parks Wales	2	Agree - No comment.	
National Parks Wales	3	Agree - No comment.	
SSE	1	We do not object per se to the proposal in respect of high status water bodies. However, we note that a part of the proposal is to recommend that the impact of artificially increased flows be considered when confirming Good status or determining what action is required to address water bodies at less than good. However, in so doing it must still be recognised that water flows in these instances are purely indicators and that the actual ecology would need to be examined to determine whether restrictions on artificially elevated flows would in fact be necessary. In any case, we believe it is important to consult on this aspect of the current recommendation to ensure that there is no unintended consequence. Furthermore, UKTAG has indicated that the current and	1. We agree that the ecological evidence should be taken in to account. We have not proposed to include thresholds for artificially elevated flows in determining Good status. Instead we recommend that, where flow in water bodies at Good (or less than Good) status is artificially elevated then the ecological evidence should be reviewed to identify if these raised flows are having an impact on the ecology. If so then this should be considered when confirming Good status or deciding what action might be required to get to Good. Consultations that will be run by the devolved administrations to enact these standards will make also need to make this clear. 2. At this stage, we have not put forward any amendments to the UKTAG Flows for Good

		separate guidance on river flows for HMWBs be revised to take account of the impact of elevated flows. Based on current understanding, this would potentially be a significant concern given that artificially elevated flows are often an integral part of an activity associated with HMWBs (e.g. hydro generation). Accordingly, if proposals are to be made to alter the HMWB flow guidance as suggested, it is vital that their occurrence should purely be viewed as indicators that warrant further investigation to determine whether or not there is, in that particular scenario, a detrimental ecological impact that needs to be addressed. Furthermore, to the extent that mitigation is considered necessary, it will be necessary to take account of the impact of that mitigation on the use of the waterbody and the associated Heavily Modified classification. As per above, it will be important for detailed consultation on this issue ahead of any proposed change to the guidance.	Ecological Potential (GEP) guidance. If amendments are proposed, these will need to be consulted on. The current guidance identifies ecologically important components of river flows likely to be ecologically beneficial and supports an approach whereby ecologically relevant mitigation for the site concerned is identified and then appraised in terms of its implications for the water use and the wider environment. We would therefore expect any future proposals for artificially elevated flows to follow this approach
SSE	2	Agree - No comment.	
Coal Authority	1	The Coal Authority is a partner UK government organisation to EA, NRW and SEPA for delivery of water quality improvements through management of mine water from legacy coal and metal mines. A key risk to delivery of water quality improvements is the potential for mine water to be classified as “artificial flow” in the context of the revised standards, rather than natural (groundwater) flow. The Coal Authority wishes to express concern as to how the UK Environmental Regulators would classify mine	UKTAG’s role is to provide recommendations to UK Administrations based on new developments in technical understandings. The proposals to take account of artificially raised flows in determining if water bodies meet high status is based on new evidence. The implications of taking account of these recommendations is a matter to be considered at a country level by the UK Administrations in deciding whether to adopt these recommendations. This would normally be included as part of the consultation on updated River Basin Management Plans. However we would point out that:

		water under these new recommendations. Although, we acknowledge that these new standards will only apply to High Status waterbodies, as hydrology can be used as a supporting element for other statuses, we foresee that this could cause issues for mine water treatment (undertaken to facilitate WFD compliance) in catchments impacted by mine water. Proposed revisions will include limits on the discharge of "artificially increased flows", which may pose a constraint on mine water management in some catchments. The revisions may add significant cost to the tax payer for delivering a mine water management scheme if, for example, mine water must be transferred into another catchment for discharge to avoid triggering artificial flow limits. Furthermore, the Coal Authority may require variations to existing discharge consents, which may not be approved in future if mine water is to be considered "artificial flow". The Coal Authority only invests in feasible schemes where benefits exceed costs. If mine waters are not exempt from this proposed standard, then there is a significant possibility that cost – benefit investment tests will be failed. In turn, this means that untreated mine waters will decant uncontrolled into waterbodies, including strategically important aquifers used for public water supply, as well as rivers. This could potentially lead to a deterioration of status in those waterbodies impacted by the new uncontrolled discharge(s). The Coal Authority is unable to support the proposals without a position statement from EA, NRW, and SEPA on	• These recommendations (for artificially raised flows) relate only to high status definition; we are not proposing to apply this to flow standards for Good status in the third cycle of river basin plans and do not plan to do so for future cycles unless new, sufficiently robust evidence is developed. Any such future changes would also be subject to consultation; • The provisions of the WFD are such that the cost implications for implementing measures in achieving water body objectives, such as you describe, are taken into account. However this would be a matter for the relevant administrative country

		the classification of mine water in the context of "artificial flows". The position statement(s) should consider the full impact of the classification and revised standards on current and future mine water management. More specifically, EA, NRW and SEPA must consider which, if any, of the following scenarios would be classified as "artificial flow": - outflow of water from mine workings by gravity into a watercourse (with or without formal outfall structure) - diversion of water emanating from mine workings and discharged into a new point along a watercourse (e.g. flow routed through a gravity-fed passive treatment scheme prior to discharge) - interception of water from mine workings and discharge by gravity to a new point along a watercourse - interception of water from mine workings at or near surface by pumping and discharge into a new point along a watercourse - interception of water from mine workings at or near surface by pumping and discharge into a different watercourse - interception of water from deeper mine workings which would, in future, outflow into one or more watercourses by gravity, or impact regionally important groundwater bodies	

		The Coal Authority recommend that UKTAG postpone revisions to the Environmental Standards until clarity on the matter is available from EA, NRW and SEPA; can consideration be made as to whether mine water discharges, either from the former nationalised coal industry or orphaned metal mines, can be exempt from the standards. The Coal Authority welcomes further discussions with EA, NRW and SEPA to assist with their position statements if required. The above issues were raised by the Coal Authority at the UKTAG Standards Consultation Webinar, held on 12th June 2019, where we were informed that the source / origin of any additional flow had not been considered in the proposals.	
Coal Authority	2	The Coal Authority supports these proposals which may allow opportunity for alternative operational practices at our mine water management schemes without triggering a downgrade of catchment classification.	
Coal Authority	3	The Coal Authority are satisfied that the approach taken agrees with the relevant EU guidance.	
Energy UK	1	We do not object per se to the proposal in respect of High status water bodies. However, we note that a part of the proposal is to recommend that the impact of artificially increased flows be considered when confirming Good status or determining what action is required to address water bodies at less than Good status. However, in so doing, it must still be recognised that water flows in these instances are purely indicators and that the actual ecology would need to be examined	1. We agree that the ecological evidence should be taken in to account. We have not proposed to include thresholds for artificially elevated flows in determining Good status. Instead we recommend that, where flow in water bodies at Good (or less than Good) status is artificially elevated then the ecological evidence should be reviewed to identify if these raised flows are having an impact on the ecology. If so then this should be

		to determine whether restrictions on artificially elevated flows would in fact be necessary. In any case, we believe it is important to consult on this aspect of the current recommendation and on the development of relevant guidance to ensure that there is no unintended consequence (including, for example, for trading and water sharing on rivers which might otherwise occur, depending on the definitions of 'artificial' and 'increase'). Furthermore, UKTAG has indicated that the current and separate guidance on river flows for Heavily Modified Water Bodies (HMWBs) should be revised to take account of the impact of elevated flows. Based on current understanding, this would potentially be a significant concern given that artificially elevated flows are often an integral part of an activity associated with HMWBs (e.g. hydro generation). Accordingly, if proposals are to be made to alter the HMWB flow guidance as suggested, it is vital that their occurrence should purely be viewed as indicators that warrant further investigation to determine whether or not there is, in that particular scenario, a detrimental ecological impact that needs to be addressed. Furthermore, to the extent that mitigation is considered necessary, it will be necessary to take account of the impact of that mitigation on the use of the water body and the associated Heavily Modified classification. As above, it will be important to have detailed consultation on this issue ahead of any proposed change to the guidance.	considered when confirming Good status or deciding what action might be required to get to Good. Consultations that will be run by the devolved administrations to enact these standards will make also need to make this clear. 2. At this stage, we have not put forward any amendments to the UKTAG Flows for GEP guidance. If amendments are proposed, these will need to be consulted on. The current guidance identifies ecologically important components of river flows likely to be ecologically beneficial and supports an approach whereby ecologically relevant mitigation for the site concerned is identified and then appraised in terms of its implications for the water use and the wider environment. We would expect any proposals for artificially elevated flows to also follow this approach
Energy UK	2	Yes – and we would encourage use of this thinking in relation to short-term exceedances of the abstraction that would otherwise be 'allowed' using the normal	

		Environmental Flow Indicator approach more generally in abstraction licensing, resource allocation and trading contexts.	
United Utilities	1	Agree - No comment.	
United Utilities	2	Happy to see the fact that fish and invertebrates are able to tolerate short-term flow reductions being taken account of. This is similar to the application of fundamental intermittent standards under the Urban Pollution Management approach.	Thank you for your comment.
United Utilities	3	Agree - No comment.	
NFU	General	**Augmented flows** This proposal is targeted at watercourses that are currently classified at 'High' status only. We understand the reasons for limiting artificially elevated flows and WFD classification and consider this has been developed from sound and valid research. Based on the information provided within the consultation document we do not see any notable impacts for landowners as a direct consequence of this specific proposal associated with augmented flows and classification as 'high' status. There are several watercourses in England that have long-established augmented flow, for example the Rivers Blackwater and Pant receive water from Ely Ouse to Essex Transfer Scheme. However, rivers that are part of notable water	

		transfer or water storage schemes are classified as a 'Heavily Modified' waterbodies. The WFD objectives for these waterbodies are given special consideration to balance potential improvements without compromising the benefits of the existing schemes, as detailed within 'River Flows for Good Ecological Potential, UKTAG 2013,' therefore are not directly affected by this proposal. **Changes to short-term abstractions** We view the increased ability to undertake short-term abstractions as a positive proposal for landowners. The improved understanding of short-term abstractions on aquatic ecology will hopefully be reflected in abstraction licensing in the near future. This will provide greater flexibility for businesses to abstract for short periods when required. The proposal (Section 2.8) indicates that short-term deviation (allowing additional abstractions) from the standard will be permitted if a number of tests are met but does not clarify this or reference the 'tests'. However, within the Annex A, Section 1.42, there are four bullet points and Table A2.2 (Current WFD status and duration of proposed abstraction). It is likely that these are the 'tests' but further clarification of this is required.	In section 2.8, we omitted a cross reference to the tests we set out in section 2.25. We thank the NFU for pointing this out and will amend the recommendations accordingly.
NFU	1	We do not disagree with the proposal to revise the definition of High status to include set limits for artificially elevated flows. It is acknowledged that waterbodies classified as 'heavily modified' are not included within this proposed re-classification and therefore the impact of the proposals are very limited.	Noted.

NFU	2	We support proposals to take account of short-term abstractions, as this is likely to provide greater flexibility in working practices and will benefit the agricultural industry. However, we'd like clarification of the 'tests' that must be met to permit short-term abstraction. We assume the tests are detailed in Section 1.42 of Annex A, but this is not specifically cross-referenced with the Consultation document.	The UKTAG agrees that tests will need to be met to permit short-term abstraction. These are listed in section 2.25 of the main document and section 1.42 of Annex A. We will update the document to ensure that this cross reference is in place.
NFU	3	We are content the approach agrees with relevant EU guidance.	
Yorkshire Water Services	1	We note the proposed changes to mid and high flow standards. We will need to quantify the impact of these new standards (if any) to our current abstraction licences, before we are able to comment on the implications. We strongly support the principle stated that changes to licences should only occur where there is corroborating evidence of ecological damage. We have followed this principle of evidence led decisions based on extensive investigations of our water resources for several AMPs. We would resist any regression towards the arbitrary application of standards with no supporting evidence as it would be impossible to quantify the benefits. We note the proposed changes to the flow building blocks. We will need to quantify the impact of these new standards (if any) to our current reservoir flow releases, before we are able to comment on the implications	At this stage, we have not put forward any amendments to the UKTAG Flows for GEP guidance. If amendments are proposed, these will need to be consulted on. The current guidance identifies ecologically important components of river flows likely to be ecologically beneficial and supports an approach whereby ecologically relevant mitigation for the site concerned is identified and then appraised in terms of its implications for the water use and the wider environment.

Yorkshire Water Services	2	We note the proposal to introduce a temporal element to flow standards such that the frequency and duration of a low flow event should be taken into consideration. This appears to be backed up by evidence and makes ecological sense.	
Thames Water Utilities	1	Agree - No comment.	
Thames Water Utilities	2	Agree - No comment.	
Thames Water Utilities	3	Agree - No comment.	
Scottish Water	2	We support these proposals, with the further comment that the Qn98 exception maybe not applicable in lowland rivers where these flows do not necessarily result in disruption in the longitudinal wetted channel connectivity, even under impacted conditions. We would suggest that different river typologies could be considered individually to ascertain if this exception should apply. For example, in the lower reaches of the River Dee (Grampian) longitudinal connectivity would not be at risk due to low flows.	Noted.

Chapter 3: Invasive Non-Native Species List

Respondent	Question No.	Remark	UKTAG Response
Guernsey Sea Farms Ltd.	4	We are only commenting on the marine Invasive species list part of the consultation. I believe we represent the views of all oyster growers who are our customers, and most members of the Association of Scottish Shellfish Growers and the Shellfish Association of GB, but we have not consulted them directly, and the two associations, in cc, may make their own response. There are species on the high impact list which do NOT pose a risk. I refer only to the species Crassostrea gigas and other marine species we have knowledge of. This is having negative impact on commercial cultivation. C.gigas is moderate risk in the main Annex B list but High risk in ER17 We believe that both should be Low risk. This would be consistent with Ruditapes philippirum (clams) and Tiostrea luteria (although I question whether the latter can still be found in the UK). This view is based on the low chance of forming 'reefs' and in areas that do form reefs the evidence is of increased biodiversity and greater abundance of O.edulis (I can cite recent papers from surveys in Holland and Denmark and Scandinavia).	The impact status of *Crassostrea gigas* (Pacific oyster) has not changed since the last standards consultation and remains on the high impact list for ER17 and moderate list for GB. ER17 have a single high impact list and do not have a moderate category. UKTAG base the listing of species on the independent and peer reviewed risk assessments for both the island of Ireland (Ecoregion 17) and Great Britain (GB). Feedback on the risk assessments can be sent to the coordinating bodies: GBNNSS. GB risk assessments. http://www.nonnativespecies.org/index.cfm?pageid=143 NNSRAI. Ecoregion 17 risk assessments. http://nonnativespecies.ie/risk-assessments/

Ulster Angling Federation	4	Clause 3.15; Addition to the high impact list following risk assessment and expert judgement: Gunnera spp. Chilean Rhubarb. We are surprised at this listing as we understand the species is readily available from gardening suppliers.	Management measures are not part of the standards consultation, and we base the listings of species on their ecological risk. We hope that alongside other legislation, such as the EU Invasive Alien Species Regulation, the listing of species on the high impact lists will drive appropriate management measures. We have listed the two species, *Gunnera manicata & tinctoria* under the generic *Gunnera* spp. to accommodate the difficulty in taxonomically separating them.
National Parks Wales	4	No additional species to add to the list.	
Inland Waterways Association	4	Not that we are aware of, but IWA welcomes the addition of these invasive species to the high impact list, as invasive species, particularly aquatic non-native invasive plants, are a major problem on navigable waterways and IWA welcomes any measures to control their spread.	Noted.
NIEA on behalf of Ecoregion 17 Alien Species Group	4	A population of the freshwater yabby, Cherax destructor has very recently been discovered in ER17. However, information on this is minimal. If is established in the wild, it should be added to the ER17 HIAS species list. It is thought that it may only be 1 discrete population which can be eradicated. Even if it eradicated, the threat is evident and it should at least be added to the ER17 alarm list. Further discussion is required at UKTAG ASG. Hopefully more information will become available to assist with this. The Japanese kelp, Undaria pinnatifida, should be considered for addition to the ER17 HIAS list. An Irish risk	The UKTAG Alien Species Group have discussed the new population and agree that it should not be added to the list at this time given that it is believed to be a single discrete population and not considered to be established in Ecoregion 17. We will add *Cherax destructor* to the Ecoregion 17 alarm list.

		assessment is not yet available but based on a risk assessment by GBNNSS and expert judgement by our Marine colleagues, it should be added to the ER17 HIAS list.	We will add *Undaria pinnatifida* to the ER17 list, with the justification of expert judgement and the GB risk assessment.
Yorkshire Water Services	4	We believe the list is appropriate.	Noted.

Chapter 4: Lake Nitrogen

Respondent	Question No.	Comment	UKTAG Response
Anonymous	5	I strongly support the idea that nitrogen can be a limiting factor for primary producers and that it should be included as a supporting element. Under the NERC GANE project we showed this to be true for upland UK lakes (phytoplankton and periphyton; Maberly et al. 2002 Freshwat. Biol. 47: 2136-2152) and Brian Moss' group found the same for lowland UK lakes (James et al. 2003 Arch. Hydrobiol. 138: 249-266). A meta-analysis has shown this to be true globally and most systems run out, seasonally, of both nitrogen and phosphorus (Elser et al. 2007, Ecol. Lett 10: 1135-1142). So it is good to move away from the hegemony of P as the main limiting factor and I support the proposal to introduce lake nitrogen standards and use it as a supporting element.	Thank you. Your comments have been noted.

Anonymous	6	I am sure you are aware of this, but some care and thought though is needed when using these values (actually the same applies to P). First the use of TN has problems because phytoplankton is a component of TN and the bioavailablity of DON is variable (this is something we are writing up under DOMAINE). A more complicated aspect is how to act on a lake having a low status in terms of N. Since the values are calculated as an annual mean (although at some sites there could be seasonal reductions), a high TN concentration (e.g. bad status) probably means that nitrogen is in excess of requirements and so reducing N might have little effect on the biological quality element such as phytoplankton. So for example in Table 4.3- phytoplankton, cells below the diagonal (ca. 49%) have a better status based on N than P and these high-status sites for N (low concentration) are the potentially N-limited sites where N-reduction would be most likely to be effective. So there is a difference between status and the measures that might be needed to improve status- for example in 4.21 you say that 9 water bodies would have a reduced status based on N than on P- but in terms of improving status you might have more success targeting P. It always takes me a few minutes to get my head round this; analysing Chla:TN and Chla:TN ratios might be helpful.	Noted - this is an issue for interpretation and investigation, rather than classification. UKTAG recognises that it will be necessary to provide guidance on how to determine the most effective intervention measures for nutrients.
Anonymous	7	You have carried out a rigorous analysis.	
Ulster Angling Federation	5	Agree - No comment.	
Ulster Angling Federation	6	Agree - No comment.	

National Parks Wales	5	Agree - No comment.	
National Parks Wales	6	Agree - No comment.	
National Parks Wales	7	Agree - No comment.	
United Utilities	5	I have said agree but it is more a case of not disagreeing.	
United Utilities	6	If standards are to be introduced happy that they will be supporting elements.	Noted
United Utilities	7	The standards that have been developed are based on broad waterbody types and don't appear to take account of the observed biology, which may be better or worse than expected. Where the existing biology is better than expected, such an approach would drive unnecessary investment to support an ecosystem that is already tolerant of the existing levels of nitrogen in the waterbody. In the opposite situation significant investment would be made and potentially no benefits delivered. Such an approach is not appropriate when further information is available to support investment decisions. An approach of using standards adjusted to match observed biology has significant benefits over and above the simple application of default standards. Firstly, it should reduce the level of mismatches between nitrogen	The proposed standards were developed from relationships between observed biological status and observed nitrogen concentrations, so this does take account of observed biology, as described in the supporting technical annex. The statistical modelling identified the lake factors that were most influential in this relationship, these being depth and colour (or humic type). Thus, UKTAG considers the application of the N standards based on these types is robust. With any derived relationship there will be a degree of uncertainty involved, and potential for a "mismatch" at the level of an individual water body, but the method for derivation of standards is designed to minimise this as far as is possible. The approach to standard derivation was developed and agreed at a European level and has been published as guidance to Member States. Simply matching current observed N to current biology would of course reduce mismatches, but would not identify a risk of deterioration of the biology in response to increased N, or conversely identify "headroom" in the N standard. Neither would matching standards to

		and biology classifications, secondly when assessing status, it should ensure, that investment is only carried out where there is a definite need with supporting evidence of adverse biological impacts with an established causative link between water quality and discharges to the water body. In addition it should also support long term planning within the water industry allowing greater flexibility in the planning of improvements.	observed biology provide any guidance on the likely reduction in nitrogen needed to result in an improvement to the biology where this is below good status. This approach to standard setting is not recommended in the European guidance we have followed.
		More investigations are definitely needed where the biology doesn't stack up with the levels of nitrogen to avoid abortive investment aimed at nitrogen removal.	The proposed standards are for classification purposes, UKTAG recognises that future identification of measures would be dependent on more detailed investigations at the water body/catchment level, and a "weight of evidence" approach that allows for inclusion of additional data sources.
		With reference to investigations and the gathering of robust data, there needs to be agreement on who collects this data, the scope of data collection required to make a robust judgement and also the funding of these investigations.	Noted, but this is not within the scope of the UKTAG consultation.
		Assessment of status using the proposed standards will not draw on all available data and mismatches between nitrogen and biology classifications will continue and it will not robustly identify needs where there is variation from the expected biology.	
		When considering new discharges the use of unadjusted standards may lead to an under or over estimate of the capacity of the receiving water to accept additional nitrogen load with the potential for either deterioration to be caused or the stifling of economic growth by	

		limiting housing development and the development of new industry. As stated above the use of adjusted standards to plan improvements to existing discharges does give benefits in terms of ensuring that investment is correctly targeted. Finally it is essential that any investment to achieve nitrogen standards must have a high confidence of yielding measureable improvement i.e. if in doubt data is gathered first and foremost then staged investment as next step.	As stated in the consultation document (paragraph 4.30): In line with its previous advice on ecological status standards for nutrients, UKTAG continues to recommend that expensive regulatory action to reduce nutrient concentrations at a site should be considered only where there is supporting evidence of adverse ecological/ biological impacts. This is the "weight-of-evidence" approach to managing eutrophication for WFD, Urban Waste Water Treatment and Nitrates Directives/Regulations purposes.
NFU	General	Whilst we understand there is a need to consider both nitrogen and phosphorus in relation to the eutrophication of lakes we do have some reservations regarding the proposals and implications to landowners. **P or N limited** Our understanding is that eutrophic lakes are either N or P limited and that this relationship is highly variable between different lake typologies and catchments. The proposals do not discuss or consider this relationship in much detail. We think this element is essential to understanding the issue and, therefore, developing suitable solutions. **Seasonal fluxes of nutrients**	Lakes may be N limited, P limited or there may be co-limitation, and the nature of the nutrient limitation may vary over time, so a direct use of this information in setting a standard is not feasible. The standards are designed to identify lakes where N is above the level that may be expected to support good ecological status. UKTAG recognises that there will be a need to conduct further investigation at a lake water body scale before

			deciding on the most effective measures, and it may be that action is then required on N, or P or both.
		The proposal only considers Total Nitrogen (TN) as an annual mean. No consideration is given to the seasonal variation and the implication of this to the growing season. It is stated that 'expensive regulatory action to reduce nutrient concentrations at site should be considered only where there is supporting evidence of adverse ecological/biological impacts'. We would like reassurance that appropriate assessments would be undertaken to identify catchment sources and suitable measures, more than source apportionment modelling as this fails to adequately identify source fluxes influenced by variable weather conditions. This approach limits the understanding of impacts and potential for remediation. In this case the significant impact from high summer point source contributions, particularly at times of low flow, are not reflected in the 'annual' source apportionment. In order to develop cost-effective improvements to the N-loading of a waterbody it is essential to understand seasonal flows and how these impact on water quality, ie to either focus on 1) reducing peak load or 2) reducing overall load. **Data records** The proposal details that the assessment of nitrogen should be based on the total nitrogen concentration (assessed as annual mean values of up to three years).	The use of an annual mean statistic reflects the overall conditions in the lake - while loadings to the lake are likely to vary seasonally, it is not only summer nutrients that drive growth, since the residence time of water in many lakes means that inputs prior to the growing season will still be available in spring. The approach of using an annual mean statistic for assessing compliance with the standard in no way limits subsequent investigation to determine sources, impacts and appropriate measures.

		We would like this element to have greater clarification and stricter requirements. Historically we have seen eutrophic lakes designated as NVZs based on only 6 months of monthly sampling or annual average calculated from only 4 samples. We think there should be a minimum sample number defined, similar to the method used in the Groundwater NVZ methodology. Where small or sparse datasets exist these should carry less weight than those with the full 12 months sampling over a 3-year period. **Boundary definitions** We consider the High/Good and Good/Moderate boundaries have been given due consideration and are based on sound research, although it is noted that many of the reference papers are >10 years old. However, the Moderate/Poor and Poor/Bad boundaries have been generated from doubling the previous value. The reasoning provided for this was scarce. We think it should be made clear that there is lower confidence in these classification boundaries.	We note the requirement to provide a specification for data to be used in classification; this will be included when a UKTAG method statement is published. Noted, we will clarify the text in the report. The Moderate/Poor and Poor/Bad boundaries are in effect guidance for management purposes, since supporting elements do not drive the reported water body classification below Moderate status.

NFU	5	The concept of a nitrogen standard for lakes is acceptable. However, the relationship with phosphorous is not straightforward. It is understood that most lakes are either primarily P or N limited. In each case we feel this should be highlighted and understood, subsequent 'weight of evidence' should be applied according to the dominant factor. The consultation does not discuss potential application of regulatory tools to meet the new standard. It is difficult to identify diffuse sources as not all stakeholders contribute equally. Implications of potential regulatory action associated with WFD lakes designated at less than 'Good' is not clear currently.	UKTAG recognises that investigation is required on a lake-by-lake basis once a classification has been produced. There is a requirement for guidance on this aspect, but this is not within the scope of the consultation. Noted, but this is outside the scope of the technical consultation.
NFU	6	As stated, the relative importance of N in each scenario must be understood. We have reservations regarding data records used to determine the 'annual averages'. Based on information associated with NVZ eutrophic lake designations, rarely is the data record complete (ie 3 years of monthly samples). Any 'weight' assigned to the 'weight of evidence' must take into account the completeness, or lack thereof, of the data record. For example, quarterly sampling provides lower confidence of an annual mean compared to monthly sampling. This should be factored in when consider the One-Out-All-Out principle.	Noted. Data quality is outside the scope of the technical consultation and is a matter for the individual Administrations and agencies. Data used for the derivation of the standards were rigorously screened.
NFU	7	The methods used to derive standards are acceptable and comparable with other EU countries.	

Anglian Water	5	In principle we agree with the introduction of standards but believe the Water Framework Directive should operate at an outcome, not a 'one out all out' level. If for example a Nitrogen standard is exceeded but elements such as biology, invertebrates, phytoplankton etc. achieve good status then the option of not taking any further action, except continued monitoring, should be implemented unless deterioration is predicted i.e. an increase or accumulation in Nitrogen load / concentration is expected. With these points in mind we appreciate the 'weight of evidence' approach in paragraph 4.30. Normal tests of cost benefit for improvements should apply and we appreciate the 'weight of evidence' approach in paragraph 4.30 and information in Tables 4.1, 4.2, 4.3 4.4 and would encourage a similar approach is adopted for each lake to which measures may apply in the future. Allowance for artificial water bodies such as water supply reservoirs should be considered as the primary role for such surface waters is for water supply not ecology; it is not clear from the consultation if standards will apply in these situations and we would ask that clarification on this is provided. In these situations sources of Nitrogen would require a catchment approach to be undertaken to reduce concentrations in water abstracted from rivers to supply reservoirs.	Changing the One-Out-All-Out approach to classification is not an available option. It is the responsibility of individual UK Administrations and agencies to determine action subsequent to classification. Noted, this is a matter for implementation and identification of measures rather than classification. As with other supporting element standards UKTAG expect these to apply to artificial and heavily modified water bodies, where there is a requirement to assess ecological potential. However, it is for individual Administrations and their agencies to decide on the use of standards in specific circumstances. We agree that a catchment approach is required for all lakes.
Anglian Water	6	Agree - No comment.	
Anglian Water	7	Please see comments on Artificial water bodies in Q5	

Yorkshire Water Services	6	We have some concerns around the proposals. Instead of table 4.1 it should be possible to present a formula relating lake depth and humic acid concentrations. This would iron out the step changes in lake typology delivered by the table. Has any consideration been given to this? As temperature is a significant factor in algal bloom production, the equation should also incorporate altitude (metres above ordnance datum) and latitude (degrees and minutes north).	UKTAG has not considered a site-specific approach to nitrogen standards because the simpler type-specific approach provides a sufficiently robust relationship between phytoplankton status and total nitrogen concentration. Where lakes are close to a type boundary we would expect this to be taken into consideration when investigations are carried out. The model is not predicting algal blooms, it is relating observed phytoplankton class to nitrogen, taking account of the most significant lake characteristics for this relationship.
Yorkshire Water Services	7	We have strong reservations about the use of total nitrogen for monitoring and management of ecological impact. Nitrogen species bioavailable to target species of algae, etc. would be a much more relevant measure in terms of ecological impact.	In lakes, it is appropriate to use total nutrient parameters, because longer residence times (compared to most rivers) mean that soluble nutrients can be incorporated into algal and other plant biomass, so very low concentrations of soluble nutrients, particularly in the summer months, will not be reflective of the true nutrient status. Lake phosphorus standards are likewise set as total phosphorus.
Thames Water Utilities	5	While we are supportive of the concept of setting environmental quality standards to protect and improve ecology, we have very significant concerns about the level of uncertainty between the proposed standards and the expected ecological quality and the implications applying such a standard will have. We query the appropriateness, let alone suitability, of establishing these standards for waterbodies such as many in the South-East of England, which are pumped storage reservoirs for potable water. Setting aside that	Relationships between nutrients and biological elements will always have a degree of uncertainty, this is unavoidable. However the relationship between nitrogen and phytoplankton used as the basis for the standard derivation, is relatively strong (r^2=0.747), and compares well to relationships used to derive other standards. The nutrient status of all lakes, artificial or otherwise, is strongly related to the supply of nutrients from the catchment. Phosphorus standards are applied to artificial/heavily modified water bodies in the same way

		these are purely artificial water bodies, application of these limits effectively establishes an unrealistic riverine N-standard (as this is the primary input to these reservoirs).	as for natural lakes, so a different approach for nitrogen does not appear necessary. However, decisions on when and where to apply the standards are a matter for individual UK Administrations and their agencies.
		This will not be addressed in any 'weight of evidence' approach but creates expectation of measures ('upstream') to address this status. Without additional information beyond the consultation it cannot be confirmed, but it seems obvious that those waterbodies with a larger catchment, particularly if with any intensive agriculture and/or sewage effluent discharges are likely to be of the poorest status. This is unlikely to impact on their fitness for purpose where we expect that P will still be the limiting nutrient.	UKTAG recognises that further guidance will be required regarding the identification of appropriate measures, and decisions on whether it is necessary to control nitrogen and/or phosphorus, on a lake-by-lake basis. A failure to meet a standard indicates a risk to ecology but does not automatically result in control measures. However, this is not within the scope of the technical consultation.
		As such setting standards for classification achieves no useful purpose – it will simply note that water quality is bad or poor. A brief review of the spatial distribution of compliance serves solely to reinforce what would confidently be expected: Oligotrophic lakes in the highlands of Scotland and Wales are of good status, with lowland sites in the more populated areas showing the poorer statuses.	UKTAG believes that setting a standard indicates where high levels of nitrogen have the potential to impact the ecology, and therefore indicates that it is a factor to be considered when evaluating potential measures.
		We note that UKTAG's remit does not extend to consider the merit of specific interventions to meet these standards and that UKTAG recommend that expensive regulatory action to reduce nutrient concentrations should be considered only where there is supporting evidence of adverse ecological/ biological impacts.	Comments are noted but are outside the scope of the technical consultation. UKTAG notes that any objectives and measures identified as a result of the application of the recommended standards would be subject to an economic cost-benefit test.

		However, we wish to highlight that if the approach used is the same as the current approach to phosphorus (as proposed), these standards are likely to lead to considerable expense (both environmentally and financially) irrespective of ecological/biological impacts This is because there is no consideration of ecology/biology when applying the “no deterioration” principle of the Water Framework Directive, even for supporting elements. As the Weser judgement sets out that no-deterioration tests are applied at an individual element level and that this should be applied as an absolute prevention of chemical concentration deterioration in waterbodies classified as bad, it can reasonably be expected to lead to investment needs to improve rivers feeding such waterbodies whenever there is a forecast for increased N inputs. Many still waterbodies receive N input either directly or indirectly from treated wastewater discharges and in many parts of the UK, particularly in South-East England, population growth forecasts even in the short term can be expected to lead to small increases in N inputs. Taking the application of the phosphorus standard as a model, this can reasonably expected lead to tighter permit limits at the upstream wastewater treatment works, irrespective of biology/ecology. For Thames Water, the risk of this is very significant given the indicative classification puts 10 of our 13 artificial pumped storage reservoirs at a “bad” classification status and these are located at the bottom of the Thames River Basin with very significant population increases forecast for most areas upstream of the intakes. Installing N	

		removal technologies is expensive in terms of capital costs, opex (particularly chemical) costs and environmentally – with significant carbon emissions associated with the probably enhanced treatment process of methanol dosing. This therefore makes setting the standards for N in lakes appropriately, accurately and with high confidence critically important to ensure investment is targeted correctly. Unfortunately, we do not have high confidence in either the accuracy or appropriateness of the proposed standards. This is for three reasons: 1. Correlation with phosphorus Given that sources of N are typically the same sources of P in the environment and where there are elevated levels of N there are likely to be elevated levels of P, there is a high risk the correlation between ecology and chemistry is mainly being driven by the growth limiting nutrient and for the other nutrient statistical correlation does not mean causation. There is little evidence presented that the two factors (N and P) have been satisfactorily disentangled. In any event, we also note the poor correlation reported in terms of classification between N, P and ecology, which lends further weight to concerns of uncertainty. In many freshwaters, the limiting nutrient is phosphorus, therefore there is a strong possibility that achieving (or protecting) the EQS for N in these cases will not result in the desired ecology in many cases. This is supported by	The relative contribution of N from different sources may be different to that for P, but this will only be apparent from site-specific investigations and source apportionment. UKTAG recognises that the interaction of nitrogen and phosphorus is complex (as is the case whenever multiple pressures are present), and we acknowledge that the identification of appropriate measures will require a consideration of which nutrient is likely to be limiting and/or produce the greatest response in any given situation. Thus, we would not expect both nitrogen and phosphorus to need control in all locations where a failure of the standard occurs. However, evidence from the wider literature, as described in the annex to the consultation document, does provide support for the

		academic studies; for example Schindler et al. (2008)1 found that controlling N could not be used as a method to limit eutrophication in lakes. We therefore believe the proposed standards have high risk of being inappropriate. 2. Low R2 values for macrophytes We note that UKTAG's statistical analysis shows a weak correlation between N concentrations and ecology with R2 values typically around the 0.4 mark. We also note that as a result that this relationship has not been used to determine EQS boundaries. While we agree that using the macrophyte correlation is not suitable for setting boundaries, this gives further weight to the possibility that N levels are not driving eutrophication risk; in which case setting standards with such uncertainty does not seem appropriate. It will also be important for economic appraisals of applying such a standard to only consider the benefits associated with changes in phytoplankton, and not those related to macrophytes. It would be helpful if UKTAG would make such a recommendation to the UK agencies responsible for River Basin Management Plans. 3. The doubling approach to EQS threshold boundaries We disagree that it is appropriate to set class boundaries for moderate/poor and poor/bad for N in lakes based on simply doubling the good/moderate boundary EQS. UKTAG's statistical analysis presented in the consultation state that there are breakpoints in the TN vs EQR	importance of nitrogen in freshwaters, and particularly in lakes. We note that in the study reported in Schindler et al (2008) the level of nitrogen enrichment was overall no higher than in the range of concentrations we propose for the good/moderate boundary standards. The standards have been derived from the relationship with phytoplankton, which returns an r^2 value of 0.747 for the best-fit model. This represents a strong relationship and UKTAG believes it is appropriate for the setting of standards. The weaker relationship with macrophytes could be due to a number of factors, including non-nutrient pressures. Comment noted. UKTAG will consider the appropriateness of such recommendations, although we would expect an improvement in phytoplankton status to have a secondary effect on macrophyte status in many lakes due to improvements in water transparency. When reporting classification, physico-chemical supporting elements do not drive status below Moderate. Although it is not necessary to set Poor and Bad boundaries for classification purposes, UKTAG have been asked to provide these boundaries by the

		relationship at 1638 µg/l for phytoplankton and 1214 µg/l for macrophytes. All but two of the proposed standards for moderate/poor boundaries are set above the 1638 µg/l level and even the lowest poor/bad EQS is nearly double this breakpoint. This means that there would be no expected ecological quality difference between waterbodies classified as poor and bad. Given the "no-deterioration" implications of class boundary changes leading to investment regardless of ecological impact, this could lead to investment to pursue standards that are divorced from ecology. In summary, we have significant concerns that these standards are not fit for purpose and as currently proposed could lead to significant investment at wastewater treatment works at considerable financial and environmental cost to prevent "deterioration" in artificial pumped storage reservoirs where there are no/negligible levels of macrophytes to protect. We recommend that further studies are undertaken to confirm the relationship between N and ecology are undertaken, and either bespoke standards are created for artificial reservoirs or exemptions apply for such waterbodies.	regulatory agencies. We will therefore recommend that the agencies take account of the uncertainty around these numbers in their subsequent planning activities.
Thames Water Utilities	6	Please see answer to Q5.	
Thames Water Utilities	7	Please see answer to Q5.	

Scottish Water	5	Scottish Water is not clear on the benefits that would be provided from applying the proposed nitrogen thresholds in relation to the ecological outcomes, given the range of other factors that may impact ecological status, notably phosphorus. Further, with the recognition there is a limited data set in Scotland on which to base these proposals, we would wish to see more analysis and monitoring to ensure that any standards are meaningful and effective in supporting improvements to ecological status.	UKTAG recognises that ecological status may be affected by a range of factors in any given lake, and that identification of the nutrient most likely to be limiting to growth is an important consideration when making decisions about effective measures. However, the wider scientific evidence supports the view that nitrogen should be considered alongside phosphorus as a cause of eutrophication. The standards have been derived using the most recent available data for the UK, covering a wide range of lake types. UKTAG considers the standards to be applicable across the UK, but as with previous standards they will be kept under review and updated should evidence become available suggesting that they can be improved.

Chapter 5: River Fish Classification

Respondent	Question No.	Remark	UKTAG Response
Ulster Angling Federation	8	We disagree with this policy as it is simply a means of relaxing standards. We believe the "one out all out" policy remains the best policy.	This proposal does not alter the One-Out-All-Out principle; instead, it seeks to address a bias that was identified in the use of the river fish classification procedure in Scotland through the second cycle river basin plan. We believe that these changes will lead to river fish classifications that more accurately reflect the impact of pressures on fish communities.
Energy UK	8	Yes – no reason to retain inconsistency with England & Wales. Only relevant to Scotland.	Noted.
Energy UK	8	Yes, generally supportive – there is no reason to retain inconsistency with England & Wales. Only relevant to Scotland. However, a consequence of aggregating sites is that it could result in run-of-river hydro plants taking further and additional measures to increase compensation flows, thereby negatively impacting renewable energy generation output from hydro-electric power stations. There is concern that any future changes of this nature could have an impact on any SEPA Water Environment Controlled Activity Regulations (CAR) licence fees, specifically the new SEPA annual fee process planned to come into effect in 2021, which factors in a "compliance factor".	The current method relies on combining results from multiple sites within river water bodies. We propose to revise the method of aggregation as we currently believe the method overestimates impacts at groups of impacted sites and underestimates the impacts where pressures are limited. The averaging approach proposed will deliver an assessment that is more representative of the conditions across the sites that have been surveyed. Consequently, we do not expect to see the outcome that has been suggested. Any further issues arising from the revision of the associated CAR Regulations can be picked up in routine liaison ahead of the Scottish Government led regulatory consultation.

		We would expect SEPA to enter into discussions with hydro operators as to how these standards will be implemented within SEPA's Water Environment Controlled Activity Regulations and the possibility of needing to review existing CAR licences.	

Chapter 6: Emamectin Benzoate EQS

Respondent	Question No.	Remark	UKTAG Response
Coastal Communities Network (Aquaculture sub-group)	9	We are surprised that UKTAG should be consulting on how the proposed EQS has been derived, because the UK's Technical Advisory Group on the Water Framework Directive can be presumed to be national experts in setting these safe levels. However, we support the basis on which these recommendations have been derived. We agree with the proposed new level for the sedimentary EQS, feeling strongly that no more leeway needs to be given than the recommended doubling of the EQSsediment presently being applied by SEPA as an interim position. When setting the MAC-EQSwater, we think the AF of 50 recommended to SEPA by WRc in 2017 should be used as a precaution, instead of the AF 10 used by UK TAG. SEPA's Scottish Pollutant Release Inventory Pollutant Fact Sheet shows that emamectin benzoate is "toxic to birds, mammals, fish and other aquatic organisms (particularly those living on the sea bed)". http://apps.sepa.org.uk/spripa/Pages/SubstanceInformation.aspx?pid=171 It is a persistent chemical in the environment, having a half-life measured in months and remaining toxic in the	It is standard practice for UKTAG to consult on all specific pollutant proposals. Thank you for the support, however the new data submitted as part of this consultation will need to be taken into account which may result in a different EQS recommendation in the revised proposal We will reconsider the available dataset and check the most appropriate Assessment Factor (AF) according to the EU Technical Guidance no. 27.

		seabed for up to 4.5 years, according to SEPA. SEPA set three EQSs for emamectin benzoate in 1999. These had remained in force until the agency adopted its current interim position. The WRc Review of Environmental Quality Standard for Emamectin Benzoate 2017 gives: • a "near-field" sediment trigger value of 7.63 µg/kg (7630 ng/kg) wet weight, which is applicable to sediment within 25 m of the marine cages, for the protection of sediment re-workers below the marine cages; • a "far-field" sediment Maximum Acceptable Concentration (MAC) of 0.763 µg/kg wet weight for the protection of all marine life; and • a MAC for the water column of 0.00022 µg/l for the protection of all marine life. The UK TAG is recommending three new EQSs for emamectin benzoate: 1. EQSsediment 2. i) MAC-EQSwater - Maximum Acceptable Concentration, for acute pelagic effects ii) AA-EQSwater - Annual Average, for chronic pelagic effects EQSsediment UK TAG is recommending a single EQSsediment of 23.5 ng/kg (dry weight). This will presumably apply at all distances from the farm up to 100m from the cage edges,	

		set by SEPA's new mixing zones. SEPA is currently applying an "interim position" EQSsediment that is even lower, at 12 ng/kg (dwt). The industry-sponsored report (Wca 2018) says that fish farms should be allowed to deposit up to 2580 ng/kg (dry weight) or 1994 ng/kg (wet weight) of emamectin in the sediment under and close to farm cages (SEPA's "near-field" EQS), and 1290 ng/kg (dry weight) or 997 ng/kg (wet weight) in the "far-field". This is more than two orders of magnitude higher than the UKTAG recommendations. The UKTAG is right to recommend a single new sediment EQS to replace SEPAs "near-field" and "far-field" sediment standards, particularly as it is unclear how SEPA derived its "near-field" EQS for emamectin in 1999, which is 10 times higher than the "far-field" EQS. UKTAG is also right to point out that it is "challenging" to set a single near-field EQS that will ensure adequate far-field protection at all farms. In fact this is nigh on impossible, as SEPA has discovered since doing so in 1999. The "far-field" EQSsediment is the equivalent of an annual average water EQS (i.e. protective of chronic effects in sediment dwelling organisms on the basis that sediment exposure is likely to be long-lived, especially in the case of persistent substances), but the near-field EQS is a regulatory construct, used more for monitoring	

		benthic impact against computer-modelled predictions, than for reducing pollution below levels that do harm. We believe that SEPA's new sector plan for aquaculture is right to no longer differentiate between near- and far-field sedimentation levels. SEPA plans to rely instead on pollution mixing zones, more accurate modelling and enhanced monitoring.	
		There is very little data on the chronic impacts of this highly persistent and toxic compound on Scottish marine species. Long term emamectin toxicity studies were only available for two copepod species, with one sub-lethal endpoint from an acute toxicity study in a polychaete species (the lugworm Arenicola marina), so UKTAG is right to also factor in the chronic exposure data for the most sensitive aquatic species, a chironomid, as a precaution. Most members of this taxa are found in freshwater but they are highly relevant to the use of emamectin on fish farms as some also live in coastal sediments, with larvae inhabiting "fully marine waters, being most abundant in the mid-littoral zone" (i.e. close to the sites of many fish farms). Chironomids are also relevant when setting the EQS, as they are known to be sensitive to emamectin benzoate's mode of action.	Thank you for your comment. Please note that additional chronic data are now available.
		Peer reviewers of the UKTAG recommendations agree that "the most critical EQS has been correctly identified in the context of impacts on benthic fauna, using the data that is available" and that "using the freshwater sediment data was appropriate for EQS setting in the marine environment in the absence of marine data."	The peer reviewers made this statement when the chironomid study was the only available chronic study. We intend to revise our proposal and get it peer reviewed. This question is highly relevant now that the dataset for chronic toxicity in sediment dwellers has been greatly extended, but the chironomid *Chironomus riparus* remains the most sensitive species.

		The industry bases its argument for setting a much higher EQSsediment on its own new chronic exposure data for two species of amphipod, but UKTAG expresses some concerns about the experimental design of some of these studies, and point out that the industry's report has failed to normalise its toxicity results relative to a standard organic carbon content, which would also reduce the EQS sediment. It correctly points out that despite these new data, and even if the chironomid data were disregarded, then "according to CIS 27, in the selection of assessment factors, chronic test data should cover the most sensitive species in the available acute studies", which is the lugworm Arenicola). UKTAG states that the limit for chronic exposure in this sediment-dwelling worm is lower than the chronic exposure limits derived from the other studies of the pelagic copepods. If UKTAG had based its EQSsediment recommendation on the lugworm rather than the chironomid, it would have recommended a "QS for sediment of 41 ng/kg dwt (rounded) based on the 10-day LC50 of 40.8 ug/kg in the lugworm (Arenicola)", i.e. double the current recommendation. In extreme contrast to this, the industry's/manufacturer's report proposes an EQS 6300% higher than 41 ng/kg dwt. UKTAG has already given some ground by exercising its expert judgement in choosing the Assessment Factor, as permitted under the Water Framework Directive technical guidance CIS 27. In part this has been possible	We believe that the shortcomings in the laboratory test data are only minor and that overall the studies have been well conducted from our review of the reports. The industry have since submitted updated results normalized to 5% organic carbon as part of this consultation (see below) Thank you for the comment. The cited figure (41 ng/kg dwt) would have resulted had no chronic toxicity data been available, following the methodology of the EU TG no.27. It was presented for comparative purposes, to put the proposed EQS (based on chronic data) in context. Thank you for the comment. We believe we satisfactorily explained why the AF of 50 was chosen with the data available at the time and note your comment.

		because including the chironomid data has reduced the uncertainty about impacts. An AF of 100 would normally apply in this case but UKTAG has chosen to use AF 50; a compromise that will allow twice as much emamectin to be discharged, compared to SEPA's interim position EQS (recommended to it by the 2017 WRc EQS proposal report (Water Research Centre Ltd 2017)) and currently applied to all new and expanding marine fish farms. The UKTAG is right not to set the EQS for emamectin benzoate any higher than this. The Scottish Salmon Producer's Organisation and MSD Animal Health have submitted their own research (Wca 2018. Derivation of Marine EQS for Emamectin Benzoate: Report to Scottish Salmon Producers Organisation and MSD Animal Health. Wca Environment and Ag-Hera. December 2018), arguing for a sediment EQS 10,000% higher than SEPA's current interim position, despite the flaws that the SSPO/MSD Animal Health sponsored report acknowledges in its own data set; for instance, as UKTAG points out, the industry's preferred EQS should not be based on a sub-lethal endpoint from an acute study of short duration. This report also omitted information from the SEPA field study (SEPA 2018), which found a significant relationship between emamectin benzoate and a decline in crustaceans. This and other uncertainties in the chronic exposure data mean the industry is wrong to suggest using the lowest AF safety margin permitted, according to CIS 27. It is not surprising that MSD Animal Health should do	Thank you for the comment, as noted in the UKTAG background document we agree with your comment in regard to the arenicola study sub-lethal endpoint.

		this; it is a division of Merck & Co. Inc., which manufactures the pesticide and will lose substantial sales if the EQS is permanently lowered, but it is hard to understand how the SSPO can justify doing so, while claiming publicly that its members use the sea sustainably. It is irresponsible for the aquaculture industry to argue for discharging such high levels of this potent and highly persistent pesticide into areas of the sea that also support commercially-important species of crustaceans, upon which the jobs of many people in economically fragile coastal communities depend. GLMM analysis of SEPA's 2018 research showed that the accumulated emamectin benzoate concentration in seabed sediments around eight Shetland farms had "by far the biggest effect on crustacean abundance and number of crustacean species", compared to total organic carbon, particle size, position relative to predominant flow direction and enrichment of polychaete abundance. The study's statistical analysis was independently reviewed by Biomathematics and Statistics Scotland. By contrast, the industry-sponsored field study (SAMS 2018) failed to find a concrete pattern. We agree with UKTAG that this is probably due to shortfalls in its experimental design, with a low density of sampling points, across a very wide range of habitats which have an inherently wide variation in crustacean diversity and abundance.	Thank you for the comment. We intend to review the field data and will request details on the SAMS study to enable a reanalysis of the data.

		This study and the toxicity studies funded by the industry must be made available to the public in full. It is ridiculous for the UK's expert body on the Water Framework Directive to consult on how it has derived the new emamectin benzoate EQS without making available the data supplied to it by the manufacturer of the chemical and its main user, which are using that data to argue for a higher EQS. The public interest surely over-rides commercial confidentiality. UKTAG says that field studies are usually "high in relevance but low in confidence" and that, although no threshold for effects could easily be derived from SEPA's Shetland study's data, the data does suggest "that a concentration somewhere in the region 10 – 100 ng/kg dwt should be protective of impacts on macroinvertebrate abundance/diversity of benthic fauna", meaning that concentrations over 100 ng/kg are likely to put that fauna at risk. UKTAG is right to conclude that the difficulties in reconciling the conclusions of these two field studies means that it must take a precautionary approach to the Assessment Factor safety margins it applies when using a deterministic approach to deriving the EQS for such a long-term persistent toxic substance, and that in this case an Assessment Factor of 50 is appropriate. UKTAG states that the industry/SAMS field study's flaws make it incapable of proving "the absence of effects, contrary to Wca environment's conclusion". This means that the industry's proposed EQSsediment is not a protective, responsible value, as claimed by the SSPO.	Please see the response below concerning release of study reports as Intellectual Property. Thank you for your comment. With the data analysis of the field studies available currently, we agree that the results seem equivocal with the inference being that differences in habitat, and so "baseline" conditions, plays a large part in this. Without extensive surveying for reference conditions for each habitat type, which would be difficult in practice, there is no easy way round this. We will request further detail on the SAMS study to enable reanalysis of the data, as stated above.

		We are particularly concerned by the lack of a true chronic study of the most sensitive marine sediment species that were used in the acute tests. Many jobs in Scotland's fragile rural economies depend on fishing for crabs, prawns and lobsters, which are virtually ignored in setting these levels. These are both reasons to take a precautionary approach.	We agree that any EQS needs to be protective of other organisms farmed or harvested commercially, although this is not the original purpose of a specific pollutant EQS.
		We note that UKTAG is expecting to receive new data from an ongoing animal toxicity study, presumably the polychaete (ragworm) study mentioned in the document, presumably also funded by the pesticide's manufacturer and the aquaculture industry, and that UKTAG will consider this data and may alter its recommendations accordingly. In that case we urge that this new data should be published and that there is a further public consultation if the UKTAG changes its recommendations on the EQS.	Under EU regulations that govern the marketing and use of chemicals, full study reports are considered Intellectual Property. However, under the other regimes study summaries that include enough information to judge reliability are generally produced that can be made publicly available. We will contact the data owners with this in mind when we review the new study data. Please see also our response to Anderson Marine Surveys.
		SEPA's rules regarding the impact of pollution in fish farms' Allowable Zones of Effect allow all but two species of polychaetes to be killed by the combination of sediment and residues of in-feed emamectin benzoate. Given that polychaetes are among the last organisms to succumb in the AZE, ragworms are not likely to be the most sensitive of Scottish marine animals to the chronic impact of emamectin benzoate. Given that emamectin benzoate is toxic "to birds, mammals, fish and other aquatic organisms (particularly those living on the sea bed)", we are concerned that the UKTAG CCT Recommendations document says: "The	We are seeking further expert advice on the relative sensitivities of polychaetes with respect to the substance's mode of action.

		mode of action of emamectin benzoate appears to have been well studied, although a later publication appears to indicate it may be relevant for a wider range of species and taxa than thought previously (see Uses of the Substance section)'. The CCT Recommendations document neglects to include this "Uses of the Substance section". Please can this omission be rectified immediately, with full references provided to the later publication? Pelagic EQS: It seems quite extraordinary, and should be a matter of censure for SEPA, that the UKTAG could not find a crucial study of the impact of emamectin benzoate on a mysid shrimp that SEPA used in 1999 to set its original pelagic EQS for emamectin, and that SEPA's workings, based on this study, have also disappeared. ("No further information than that in WRc 2017 is available, nor is further detail on the previous SEPA review available.") As a result, UK TAG has had to discount the data showing the greatest sensitivity and instead has based the new pelagic EQS on a single study (the "mysid shrimp acute toxicity study (EPP, 2018)"), funded by the industries that will benefit from being able to discharge this toxin into the environment, despite this study having "some issues with test solution analysis and lack of a test concentration causing significantly >50% mortality..." and "issues around test substance exposure concentration validation".	This is part of the UKTAG background document consulted upon, not a separate document. We are unable to offer an explanation for these data and the assessment being unavailable. We are satisfied the new test has been well conducted to internationally recognized standards, and so its results are suitable for hazard assessment. The difference in results is fairly typical of laboratory ecotoxicity testing, generally cumulative result of many small biological and water chemistry differences. Standard tests are designed to minimize these differences and aid reproducibility, but when dealing with living systems there will always be uncontrollable variability

		Accordingly, the UKTAG is recommending that the pelagic MAC-EQSwater for emamectin should be doubled to 96h LC50 of 0.078ug/l, versus the 96h LC50 0.04ug/l that was derived from the now-missing study previously used by SEPA to set this EQS. i) Acute effects - MAC-QSwater (Maximum Acceptable Concentration)	
		The UKTAG says that in the 2017 WRc EQS proposal report used by SEPA to set its interim position, "the EQS for acute effects in pelagic organisms is based on an acute toxicity study in mysid shrimp with an AF of 50, while the EQS for chronic effects uses a chronic study in the same species and an AF of 20." The UKTAG is now recommending an AF of only 10 for the acute MAC EQSwater, arguing that this is acceptable because it has also included toxicity data for Nephrops, which introduces a third level in the food chain and "because this species is significantly different from the other crustacean (copepods), having a different feeding strategy."	Please see our response above
		We do not think an AF of 10 in this case is justified. Even the industry's own proposed new MAC-EQSwater (in Wca 2018. Derivation of Marine EQS for Emamectin Benzoate: Report to Scottish Salmon Producers Organisation and MSD Animal Health. Wca Environment and Ag-Hera. December 2018) argues for an Assessment Factor of 50 rather than 10. Larval crustacea are especially sensitive to pesticides, but this assessment seems not to include any impacts on the	Please see our response above. The industry derivation took the AFs as used in the WRc report without any scrutiny of the dataset, because the focus of that review was the sediment EQS (please refer to SSPO submission).

		pelagic larvae of commercially-fished Scottish species. Nephrops adults feed on organic material in and on the sediment, rather than on invertebrates in the water column, where the pelagic impact of emamectin benzoate would be greatest. If the Nephrops study was done on pelagic larvae a reference should have been provided. Using AF 10 leaves a very small safety margin as a precaution to protect Scottish pelagic animals, including the pelagic larvae of commercially-fished species, and assumes a level of confidence that is contradicted by the UKTAG's statement that its "reviewers generally felt more evidence was needed on the reliability of the two saltwater studies used to derive the two pelagic EQS, since the test reports were not available for scrutiny". For these reasons we think the AF of 50 recommended to SEPA by WRc in 2017 should be used as a precaution when setting the MAC-EQSwater. ii) Chronic effects - AA-EQSwater (Annual Average) The UKTAG disregards two studies that showed impacts on aspects of the mysid shrimp lifecycle at low levels of emamectin (4.13ng/l and 7.84ng/l), and at one higher dose (17.07ng/l), saying: "on balance, CTT thinks that the EC10 of 9.44ng/l for reproduction is the key endpoint to take forward for hazard assessment." As there is only data for impacts on two levels in the food chain, the CIS guidance on the Water Framework Directive obliges the use of an AF of 50.	Thank you for your comment. We recognise that different life stages can have different sensitivities and exposures. We will consider this comment alongside the available data and where we have data on different life stages consider this in relation to the proposed EQS. UKTAG were tasked with deriving EQS protective of the marine environment as a whole, in accordance with the protection goals of specific pollutants under the WFD. The focus is therefore on organisms in the wild, although by extension farmed organisms should also be protected by the EQS set because of the hazard assessment paradigm followed in the EU. Please see response above. Please note these values are from the same study, they are just different endpoints measured in the study that showed equivocal statistical response (meaning the apparent effect at these concentrations could not be demonstrated with sufficient certainty). This is why we chose the slightly higher endpoint value as representative of the toxicity observed in this study.

		We agree that it is correct to use the higher AF rather than AF 10, or the industry's non-standard recommendation of AF 20, and that the CTT's recommended AA-EQSwater of 0.19 ng/l should be adopted. We absolutely agree with this overarching statement in the UK TAG Chemistry Task Team (CTT) Recommendation for an EQS for Emamectin Benzoate: "… given the inherently greater level of uncertainty in hazard assessment for the marine environment compared with the freshwater environment based on the greater number of (untested) taxa, a more precautionary approach can be justified." This is particularly true because the chronic impact of emamectin benzoate has hardly been tested on adult or larval crustaceans, which are caught for food in Scotland; either on its own or in "cocktails" of other compounds including hydrogen peroxide, which is not licensed by SEPA despite more than 19 million litres being discharged into the sea from fish farms and well boats in 2017.	Noted.
Coastal Communities Network (Aquaculture sub-group)	10	Emamectin benzoate is one of the fish farm chemicals investigated by the on-going PestPuls study in Norway. Evidence from this study shows that the use of multiple chemicals can produce significant "cocktail effects" on non-target organisms, in particular in combination with hydrogen peroxide. The lead researcher of this study is Renee Bechmann,	The current risk assessment paradigm considers chemicals individually, only occasionally are mixtures of chemicals considered in terms of effects (e.g. 6 PBDE congeners, dioxins/dioxin-like furans and PCBs). Much work internationally is going on in this field, including under the WFD with investigations into "effects based methods", but even so we understand that the state of the science does not seem mature enough for use in

		from the International Research Institute of Stavanger (IRIS). Her e-mail is: rebe@norceresearch.no She has a UK collaborator, Paul Seear, from the University of Leicester. Does UKTAG take account of the cumulative "cocktail effects" of the use of multiple chemicals? This is especially relevant to emamectin benzoate, because of its long latency in the environment, and it is a further reason to apply high precautionary Assessment Factors, when settings EQS for this compound.	regulation just yet. Thank you for the information on the PestPuls study, we will look into this.
National Parks Wales	9	Agree - No comment.	
National Parks Wales	10	No additional data.	
National Trust for Scotland	General	We very much welcome the UKTAG review which endorses the conclusions of SEPA that Emamectin Benzoate has the potential to cause substantial harm in the marine environment, including the death of a wide range of invertebrates, and that the permissible levels need to be substantially reduced. However, the levels for sediment proposed by UKTAG (23.5 ng/kg DW), are approximately double the interim guidance issued by SEPA (12 ng/kg DW) and we would question why this was felt appropriate. We are particularly concerned that the available evidence suggests that the widespread Arenicola lugworm, a keystone species in soft sediments, providing vital	The proposed EQS is double the interim guidance supplied by SEPA because more chronic toxicity data in sediment dwelling organisms has become available since that position was set. These additional data mean a lower, less precautionary assessment factor is justified, although the same study has been used. Although there are no chronic studies in Arenicola, based on the

		structural services, is apparently the most sensitive to toxicity. We would therefore urge that a highly precautionary approach is taken to the EQS for this chemical. We are also concerned that studies carried out by the industry to justify requests for a more lenient EQS have apparently been denied public access for reasons of commercial confidentiality. In particular, the industry recommendation that the EQS should be about 100 times higher (1290 ng/kg DW) than the interim guidance developed by SEPA is simply not credible in view of the widespread ecosystem damage that has already been observed. We are also perturbed that Paragraph 6.9 indicates that further data resulting from more recent studies (presumably the additional industry-funded study referred to in Paragraph 6.3 v) is expected to become available during the consultation period and will be taken into account. We would request that before this is used to justify a relaxation in the EQS a further full public consultation should be undertaken. It should also be a prerequisite that all documentation of the scientific studies underpinning this should be made publicly available, and for the full period of the consultation.	chemicals mode of toxic action we believe the tested midge species is more sensitive than the lugworm and so the EQS is protective of arenicola. We note and understand these concerns. Please see our response to the Coastal Communities Network. With respect to making studies publically available, please see our response to Coastal Communities Network above.
SSPO	9	This is a joint submission from the Scottish Salmon Producers' Organisation (SSPO) and MSD Animal Health. Due to the size of the attachments I have had to divide our response into two emails. A second email will reach you shortly, containing a single attached document (a	Please see responses to your detailed summary comments below. Please note that Table 1 lists all the detailed comments on the UKTAG background document that you submitted so that they are publicly available.

		reference: Bridges et al 2017). Please consider the entirety of this email (and the subsequent email) and all attachments as our full response to questions 9 and 10 in the response form. It is important to state that we do not agree with the derivation of the EQS being recommended by CTT. Furthermore, we are aware of additional data that is available for the derivation of the EQS, details of which are provided in our response. Please note that at no point in SSPO discussions with SEPA, which were held to support the research specifications, to ensure validity and accuracy of the industry commissioned research for a UKTAG submission, was the necessity of insect assessment in the marine environment raised. This 'oversight' was further supported by the over 20 years' worth of routine evidential field work undertaken by industry as part of licence compliance environmental monitoring where an absence of relevant insect presence from the thousands of benthos samples taken is demonstrated. Consequently, the additional information we have now presented was not considered a necessity in the previous stages. Additional to our response, we would like to offer a suitable individual(s) from our team to attend and present the new data at the next UK TAG meeting. The 95% confidence intervals for acute LC50 values for Arenicola (26 to 201 µg/kg dw) and Corophium (0 to 578	Thank you for this offer. We agree that the confidence intervals do overlap but at the same time the wide interval, especially for the

		µg/kg dw) overlap substantially, which provides no evidence for a statistically significant difference in the acute sensitivity of the polychaete Arenicola and the amphipod Corophium. The chronic data therefore cover the most sensitive species in the available acute studies because there is no difference between the tested species. The freshwater midge studies are not appropriate for the derivation of a saltwater sediment EQS. b. The use of the freshwater midge studies for the derivation of a saltwater sediment EQS is justified by CTT on the basis that insects with interdidal/marine aquatic larval stages are known in the UK, namely Clunio marinus. This rationale is dubious for the following reasons: i. The sole relevant reference to marine insects cited by CTT is to a paper by O'Reilly (2008). This is a one-page article published in The Glasgow Naturalist. In this article the author describes how: "During a warm, balmy, summer's evening on August 8th 2005, and again on August 13th 2006, an excursion was made to the shore at Wemyss Bay, in the Firth of Clyde." On these excursions, O'Reilly noticed chironomids "dancing near rocks at the water's edge", caught a few of them, and identified them as Clunio marinus. This interesting note by an enthusiastic naturalist does not constitute a "survey in the west of Scotland" as stated by CTT. No information on the wider distribution of Clunio is presented by CTT, so they have no way of knowing whether this single Scottish marine insect species occurs in any locations close to fish farms or, if it does, whether there is any	Corophium study, does not give us confidence that the statistics are representative and would suggest they are actually not that helpful. This could indicate that actually a chronic study in Arenicola should have been considered. Thank you for your information. We are seeking further expert advice on this aspect of the derivation.

		evidence that it has been, or could be, adversely affected by exposure to emamectin. ii. The doubtful status of Clunio's presence in Scotland, including salmon farming areas, is highlighted by the following findings: • Clunio marinus is listed both in the World Register of Marine Species (WORMS) and the Marine Species of the British Isles and Adjacent Seas (MSBIAS) subset. Consequently, Clunio marinus is included in the Marine Recorder dictionary. However, there are no records for Clunio marinus in the Marine Recorder. • The NBN Atlas indicates four "Accepted" records (and no "Unaccepted" records) (https://species.nbnatlas.org/species/NBNSYS0000027483), but none of the records is at a location where salmon farming occurs (with one location being at Tarbat Ness on the Scottish East Coast). • The Ocean Biogeographic Information System (OBIS) maps the taxon as present in the Clyde, but that system does not appear to have the ability to query the source of the record(s) concerned [https://obis.org/taxon/118146]. However, based on the general geographical location, this record most likely refers to the publication by O'Reilly (2008). iii. It is correct that most of Clunio's life history is associated with the marine sediment. However, it should be noted that its distribution is strictly limited to the intertidal zone (i.e., seabed that is covered and uncovered by the sea according to the rise and fall of the tide). Larvae move to the lower fringe of the eulittoral zone which is submerged at normal tides and is exposed only at springtides (Kaiser et al. 2011).	

		iv. To the best of our knowledge this is the first time that CTT has expressed an interest in focusing a saltwater risk assessment on protecting insects. This interest has clearly only arisen because of the prior existence and use of freshwater sediment insect data. If CTT had been presented with only the saltwater sediment dataset for crustaceans and polychaetes then this would have exceeded the data requirements for setting a saltwater sediment EQS, and CTT would not have asked for any additional testing of freshwater sediment species. v. Clunio marinus is cultured in laboratories for use in chronobiology studies and so could have been tested toxicologically if there had been any great desire on the part of regulators to focus an EQS on protecting this species. Instead, discussion between industry and regulatory authorities has been entirely about testing saltwater crustacean species. At no point has industry ever been asked to test marine insect species and yet we are now potentially about to be regulated on this basis. c. As the presence of Clunio marinus is strictly limited to the intertidal zone, freshwater insect data are not relevant for the derivation of a marine EQS if this EQS is meant to protect subtidal benthic faunal communities, or if this EQS forms the basis of a mandatory monitoring program in which sediment is collected only from the subtidal zone. The freshwater midge studies are not appropriate for the derivation of a saltwater sediment EQS. a. Statistical comparison of the freshwater sediment toxicity data (which includes the two midge values) with the saltwater sediment toxicity data (for crustaceans and polychaetes), using the CIS 27 methodology, shows that	Thank you for this comment. However this study is available, and technical guidance directs us to use all available reliable and relevant information (with reference to your comment above). Only very recently has further chronic ecotoxicity test data on organisms representative of the exposed environmental compartment that forms the basis of the industry's regulated medicine use become available. Thank you for this information. We were not aware this species was cultured and so potentially available for toxicity testing. Please see our response to Anderson Marine Surveys with regard to protection goals and EQS for specific pollutants. From a preliminary look at the new data, we agree the statistical difference is mostly a product of the presence of the two chironomid species in the freshwater dataset, when no similar taxa are present in the marine. We had a similar situation with the pelagic data where reanalysis by one of the peer reviewers showed that the apparent

		the freshwater sediment data are significantly different in their sensitivity to emamectin and should therefore not be pooled with saltwater crustacean and polychaete sediment data. This difference is driven by the two chironomid values, which are much lower than the toxicity values for all other taxa, including the freshwater sediment-dwelling crustacean H. azteca. 2. An F test to compare variance homogeneity between the freshwater and saltwater values, as required in CIS 27, produces an F statistic of 0.84 and a p value of 0.913. The variances of these two groups are therefore statistically similar and it is appropriate to continue with a two tailed t-test performed at a significance level of 0.05. This t-test produces a t statistic of 2.97 and a p value of 0.041. The null hypothesis that the sensitivity of freshwater and saltwater sediment organisms is similar is therefore not supported and the two datasets should not be combined 5. CTT is incorrect to invoke the principle of "greater uncertainty" in hazard assessment for the marine environment in the case of emamectin. There is, in fact, a smaller degree of uncertainty in the hazard assessment of this substance when compared with a wide range of other substances released to the aquatic, and especially, marine environment. This is because the mode of action and target receptors for abamectins are specific and very well known, and there is an extensive sediment test database available for these specific target receptors and emamectin. Benthic taxonomic groups that have not been tested, namely echinoderms and cnidarians, are	statistical difference was down to differences in taxa between the datasets, rather than differences in sensitivities between similar organisms. We will consider this further in the revised proposal. Please see our comment above in relation to the pelagic dataset. Thank you for the comment. We will consider this further as part of an extended Memorandum of Agreement consideration in revised proposal

		likely to be less sensitive due to their lack of glutamate-gated chloride channels (Wolstenholme 2012).	
		Throughout the document, sediment toxicity data are expressed as sediment dry weight (dw). The results from the field studies are expressed as sediment wet weight (ww).	Thank you for this comment. We will take this into account in any revised proposal.
		7. When anomalous data are removed from SEPA and industry field study datasets there is no evidence to suggest that emamectin concentrations up to approximately 1 µg/kg ww would adversely affect crustacean populations. Interestingly, this is similar to the concentration at which no effects are observed in the most sensitive sediment toxicity test (C. riparius). This value derived from field data is considerably more than an order of magnitude greater than the EQS proposed by CTT, so CIS 27 recommends that the size of the assessment factor should be reviewed. If the ww/dw concentrations reported by SEPA (Table 4 of their Fish Farming Report [SEPA 2018]) are used in EQS derivation, the average moisture content is 38.4%. Using this average, an EQS of 1 µg/kg dw equals 0.61 µg/kg ww. Accordingly, an EQS of 1 µg/kg dw will be well below the concentration that has been shown to cause no effects in field studies (i.e. 1 µg/kg ww).	Thank you for this information. We would like to understand whether the statistical procedure work (removal of anomalous data) that you describe was undertaken after your submission of the data packages for UKTAG's review? If so, we could this work also be shared with us?
		8. In conclusion, we would support the derivation of a saltwater sediment EQS based upon the most sensitive saltwater sediment value (organic carbon normalised Corophium NOEC of 53.3 µg/kg dw) and an AF of 10, which produces an EQS (rounded down) of 5 µg/kg dw. However, evidence from field studies should also be	This approach is very different from that proposed prior to the consultation. We understand a large reason for this is the availability of further ecotoxicity data, but still going from an AF of 10 on a sub-lethal endpoint in an acute study to an AF of 50 for a chronic NOEC in a larger dataset, when no new field data are available, seems a

		taken into account when setting an EQS and these studies demonstrate safety below a concentration in the region of 1 µg/kg ww, with less certainty above this concentration. We therefore propose that for additional safety an AF of 50 is applied to the Corophium NOEC and that value is then rounded down to an EQS of 1 µg/kg dw. This value is lower than the NOEC for the most sensitive freshwater species that has been tested (C. riparius) and would therefore also protect this species	big change. We will review all the new data, further consider the relevance of the insect data and consider the protection goals of EQS for specific pollutants, as discussed in the previous sections.
		This response to the recent UKTAG documents on a revised emamectin benzoate EQS focuses on the derivation of a marine sediment EQS and the two main documents that deal with this: • Background Report - CTT recommendation for an EQS for emamectin benzoate.pdf • Background Report - CTT comments on 2018 industry sponsored EQS derivation report for emamectin benzoate.pdf We take a detailed approach in this response, addressing each statement or collection of statements within the relevant sections of each report. Our conclusions are presented first, followed by specific responses to the statements (Tables 1 and 2 below)	Thank you for the comments. Your detailed responses, tables 1 and 2, are included in the following sections. We have addressed your comments here in relation to your summary comments but cover some areas not in the summary below.
		In accordance with CIS 27, sediment toxicity data are normalised to a standard sediment defined as having an organic carbon content of 5% (w/w). OVERALL CONCLUSIONS 1. The following chronic sediment toxicity data are available for emamectin benzoate: a. Freshwater sediment endpoints:	Thank you. We have checked your workings and agree with the values, apart from that for chironomid study (OC value in the study was higher than that which you have used, at about 4.5%).

		i. Log10 OC-normalised C. riparius NOEC value of 2.6 µg/kg dw = 0.415 µg/kg dw ii. Log10 OC-normalised C. dilutus NOEC value of 4.8 µg/kg dw = 0.681 µg/kg dw iii. Log10 OC-normalised H. azteca NOEC value of 43.2 µg/kg dw = 1.635 µg/kg dw b. Saltwater sediment data: i. Log10 OC-normalised L. plumulosus EC10 value of 492.87 µg/kg dw (based on geomean of two studies) = 2.693 µg/kg dw ii. Log10 OC-normalised C. volutator NOEC value of 53.3 µg/kg dw = 1.727 µg/kg dw iii. Log10 OC-normalised H. diversicolor NOEC value of 617.9 µg/kg dw = 2.791 µg/kg dw	
SSPO	10	In addition, the existing data set of marine studies is completed by a chronic study with the polychaete Hediste which removes any earlier concerns that a chronic study was not available for the apparently most sensitive taxon in acute studies. 6. CIS 27 Table 5.3 specifies an assessment factor of 10 if there are "three long term tests with species representing different living and feeding conditions including a minimum of two tests with marine species." These conditions are met by the available dataset in which the following four long-term sediment tests are available for crustacean and polychaete species with different living and feeding conditions, with three tests for marine species: a. Leptocheirus: burrowing surface deposit-feeding amphipod (Bridges et al 2017)	We appreciate the industry's efforts in enhancing the dataset with representative species. We have a concern based on anecdotal evidence that the ragworm may be a less sensitive species than the lugworm. We are seeking independent expert advice on this aspect of the dataset. We will consider the extended dataset, relevance and differences in living/feeding conditions further as part of the revised proposal.

		b. Corophium: burrowing suspension and surface deposit-feeding amphipod (Gerdol & Hughes 1994) c. Hediste: burrowing predatory and scavenging polychaete (Costa et al. 2006) d. Hyalella: epibenthic grazer and surface deposit-feeding amphipod (Strong 1972).	
Biotikos Limited	9	This derivation is based on **fresh water, in vitro, in solution**, Ecotoxicological analyses based on an **insect species**. The results are being proposed for utilisation in monitoring **marine** fish farms and extrapolated to encompass a **wide variety of crustacean species** in **sediment**. I have no confidence that this is an appropriate basis for setting an EQS in this environment.	Thank you for your comment. In addition to the response above, please note that the EU TG no.27 recommends relevant freshwater and marine data be pooled unless there is a statistical difference between the two datasets. Your question refers more to relevance we believe, as is discussed.
Mowi Scotland Limited	9	No, we do not support how the proposed EQS has been derived. We would refer to (and support in full) the detailed response (and additional scientific data) submitted by the Scottish Salmon Producers Organisation (SSPO) on behalf of its members. This provides a detailed point by point response to the previous CTT reports on the derivation of the proposed EQS outlining the areas of concern and how information gaps have been addressed. We would request a review of the previous CTT assessments undertaken in light of the detail and new data presented in this additional response. We do not wish to repeat the conclusions of SSPO response but we do wish to highlight a key concern which we believe is unreasonably influencing the derivation of the proposed EQS.	Previous Chemistry Task Team (CTT) assessments – the proposal of EQS for UK river basin specific pollutants – followed EU technical guidance and were subject to peer review prior to consultation. We do not believe a wholesale review of them is necessary.

		Specifically, we do not believe that freshwater midge studies are appropriate for use in the derivation of a marine sediment EQS. The use of freshwater midge studies has been justified by the CTT on the basis that insects with marine aquatic larval stages (namely Clunio marinus) are known to be present within marine environments in the UK. Notwithstanding the significant concerns and the lack of any robust peer reviewed scientific data on the status or distribution of Clunio's presence in the marine environment in Scotland we can offer our direct observations generally on the presence of marine insects in the benthic environments around our fish farms. Mowi Scotland is the largest fish farm operator in Scotland and undertakes approximately 35 benthic surveys a year at fish farm sites across a wide geographic spread on the West coast of Scotland with locations ranging from enclosed loch waterbodies to true open sea environments. These surveys are carried out for both our statutory compliance requirements and for own site management reasons purposes and includes detailed taxonomic analysis of sediment samples. We have accumulated an extensive library of data on biological taxa going back many years; with this data notably also being in the public domain having been submitted to SEPA as per regulatory requirements. From a taxonomic point of view, insects will be recorded within our monitoring reports if identified within our samplings (this is a requirement as part of the NE Atlantic Marine Biological Analytical Quality Control Scheme and	Thank you for your comment. Please see the response to the similar comment from Loch Duart in relation to survey data and our response to the similar comment from Anderson Marine Surveys in relation to protection goals for specific pollutants.

		good-practice). Insects however would potentially only be in found intertidal areas subject to significant brackish/freshwater influence so would generally be a result of washouts. They are not part of an active community in the benthos for fully marine environments and a review of our benthic reports confirms that insects are not generally found anywhere close to our farm environments and are only identified in extremely rare occasions. Intertidal species such as insects have not previously been identified as a protection goal for an emamectin benzoate EQS. There are, at present, no regulatory requirements for intertidal sediment sampling for emamectin benzoate residues. The focus on marine insects appears to be solely because of its previous and earlier focus as part of EQS derivation. There are now sufficient saltwater sediment data sets for crustaceans and polychaetes that would appear to satisfy the data requirements for derivation of a marine EQS. As such we question the appropriateness of continued reliance and use of freshwater insect data in the derivation of a EQS for emamectin benzoate. Summary As the presence of Clunio marinus is strictly limited to the intertidal zone, we are strongly of the opinion that it is not appropriate to utilise freshwater insect data for the derivation of a marine EQS noting that the purpose of the EQS is to protect subtidal benthic faunal communities. We would contend that the available evidence on the presence and distribution of Clunio in the benthos surrounding farm environment does not support this	Please see our responses to SSPO

		approach. The available data sets from fish farm monitoring indicate an absence of Clunio from fish farm environments (which are submitted to and directly available for SEPA to confirm). This evidence forms a stronger weight of evidence than the justification that the CTT has attributed to the very limited survey data on presence / distribution of Clunio in Scotland, arising from the referenced single page paper on Clunio (O'Reilly 2008).	
Mowi Scotland Limited	10	There is now additional ecotoxity tests available to add the previously available data sets and I would refer to the additional detail and studies submitted by Scottish Salmon Producers Organisation, namely: 1. Emamectin benzoate: determination of chronic toxicity in a 28-day growth study with the ragworm Hediste diversicolor; 2. Life cycle toxicity of the active ingredient emamectin benzoate to the sediment-dwelling midge Chironomus dilutus; 3. Life cycle toxicity of the active ingredient emamectin benzoate to the amphipods Hyalella Azteca. The new data sets addresses a key point raised by the CTT that there was not enough data to distinguish differences in sensitivities between freshwater and marine sediment dwelling organisms, a justification for the previous pooling of data.	Thank you. We will be reviewing these studies as stated above, subject to the necessary data being made available. Please see our comments in the previous section in relation to the statistical differences between the datasets.

Anderson Marine Surveys Ltd	9	The background information presented by CTT on emamectin benzoate is minimal and does not recognise some key points relating to mode of action, toxicology and consequent environmental effects. Specifically, emamectin is a binder to GABAA receptors which are widespread in invertebrate and vertebrate animals; the focus on arthropod taxa is therefore inappropriate. Both GABA and GluCl receptors function as ion channels and there is therefore reasonable cause to expect emamectin effects to vary significantly between fresh water and marine environments and organisms; in which ionic gradients across neuronal membranes will be very different. Both WRc (2017) and CTT (2019) conclusions regarding combining the freshwater and saltwater ecotoxicity data on the basis of no obvious differences in sensitivities and knowledge of the substance's toxic mode of action, are not justified. 3. Inclusion of the freshwater chironimid chronic toxicity data in derivation of the sediment EQS is fundamentally incorrect. As noted above, there are good reasons to consider that both the habitat and taxonomic/physiological distinctions between Chironomus riparius and marine benthic organisms relevant to the EQS are significant. CTT's justification of the relevance of Chironomus data, based on a single intertidal record of Clunio, is both ecologically and hydrodynamically simplistic and naïve. Insects have no relevance whatsoever to the structure and function of marine benthic invertebrate communities. CTT's statement "In terms of exposure, many fish farms are situated in sea lochs or coastal waters that are protected from the rigours of the open sea; hence they are almost	Thank you for this comment. We will further investigate this aspect and take expert advice on invertebrate physiology with respect to the substance's mode of action, including likely relative sensitivities between fresh- and marine water organisms We think there is a wider issue that needs to be addressed. We are seeking further expert and policy advice on the use of this study in relation to the protection of the marine environment, considering not only representativeness and potential for exposure but also what the protection goal of Specific Pollutants with regard to the marine environment actually means. In previous derivations, marine standards for specific pollutants have been taken to be protective of all marine environments, including transitional and coastal waters. We think the narrower protection goal to which you allude may represent something different to that for which a specific pollutant is derived.

		always in tidal zones such that sediment exposure to fish faeces deposition or other releases from the cages can occur both up- and down-gradient. This means that sediment exposure can occur in areas between cages and the shoreline, not just in areas between cages and the open sea." [p17] is confused and meaningless, in relation to the well-characterised dispersion of particulate wastes from marine aquaculture sites. There is no evidence, or reasonable cause to expect, significant exposure of insects in intertidal sediments to emamectin residue originating from aquaculture. 4. Inclusion of the Arenicola 10-day casting data is also dubious. CTT correctly question the derivation of the EC10 sub-lethal endpoint; a conclusion that "the results seem to indicate an effect is occurring" [p14] is not sufficiently robust to support the derivation of an EQS. 5. In view of the above, the correct outcome of the CTT flowchart (Figure 1) should be a QS of 305 ng/kg (two MW amphipod datasets with AF of 100); noting that this does not account for more recently available datasets. If the Arenicola dataset is included, the AF should be 50; giving a similar QS of 258 ng/kg. 6. CTT correctly conclude that the SEPA field study does not support a threshold for effects of emamectin. Re-analysis of the SEPA (2018) dataset shows that there is no basis to conclude that crustacea are more effected than other taxa; that there were uncontrolled habitat variables which preclude an unambiguous assessment of emamectin effects using GLMM or CCA; and that contrasting conclusions can be drawn from this dataset	Thank you for the comment. We agree with regard to the use of this study's sub-lethal endpoint. Thank you for the comment. We agree with regard to the use of this study's sub-lethal endpoint and we would be interested in seeing your reanalysis of the data. We intend to review further the two available field studies as part of revised proposal.

		based on arbitrary inclusion of sites. 7. Overall, it is surprising and concerning that both SEPA and UKTAG should derive recommendations of such consequence for the aquaculture industry, from such sparse and irrelevant datasets. The limited available data of ecological relevance, from two very similar corophiid amphipod species, supports a chronic sediment EQS of around 305 ng/kg (dry weight), so not significantly different to the previous EQS of 760 ng/kg wet weight, assuming sediment water content of 40-50%. The previous EQS should therefore be retained, pending review of the additional data recently provided by industry.	Please see our responses to your comments above, which also indicate what steps we will take next to produce a revised proposal for this substance
Anderson Marine Surveys Ltd	10	CTT appear to be uninformed of ongoing work undertaken by the industry, specifically to provide a wider range of test organisms relevant to the review. The CTT review and recommendation should have been delayed to take account of this additional data. SEPA and/or UKTAG should have commissioned or undertaken independent studies to address the data gaps (which have been clearly recognised for a decade). As it stands, the CTT recommendation is based on inadequate and outdated information.	We were aware that one new study was being conducted in a polychaete species, but not that additional freshwater studies would also become available. As stated above we will be reviewing all the new data as part of the revised proposal. Conducting ecotoxicity testing is expensive and beyond the resources, especially in the case of chronic studies, nowadays of public bodies. Following the paradigm of EU regulations like REACH, plant protection product, biocides and veterinary medicines, it is up the registrant seeking to market a substance to conduct the requisite testing to ensure the product's safety for humans and the environment based on exposure routes and substance properties. The fact remains that the way in which this substance is used results in large quantities of what is a highly persistent chemical being releases to the marine

			environment, with few if any comparable situations for other veterinary medicine uses.
Wester Ross Fisheries Ltd. in cooperation with Anderson Marine Ltd.	9	The background information presented by CTT on emamectin benzoate is minimal and does not recognise some key points relating to mode of action, toxicology and consequent environmental effects. Specifically, emamectin is a binder to GABAA receptors which are widespread in invertebrate and vertebrate animals; the focus on arthropod taxa is therefore inappropriate. Both GABA and GluCl receptors function as ion channels and there is therefore reasonable cause to expect emamectin effects to vary significantly between fresh water and marine environments and organisms; in which ionic gradients across neuronal membranes will be very different. Both WRc (2017) and CTT (2019) conclusions regarding combining the freshwater and saltwater ecotoxicity data on the basis of no obvious differences in sensitivities and knowledge of the substance's toxic mode of action, are not justified. Inclusion of the freshwater chironimid chronic toxicity data in derivation of the sediment EQS is fundamentally incorrect. As noted above, there are good reasons to consider that both the habitat and taxonomic/physiological distinctions between Chironomus riparius and marine benthic organisms relevant to the EQS are significant. CTT's justification of the relevance of Chironomus data, based on a single intertidal record of Clunio, is both ecologically and hydrodynamically simplistic and naïve. Insects have no relevance whatsoever to the structure and function of marine benthic invertebrate communities. CTT's	Thank you for this comment. We will further investigate this aspect and take expert advice on invertebrate physiology with respect to the substance's mode of action, including likely relative sensitivities between fresh and marine water organisms. Please see our response to Anderson Marine Surveys regarding this point.

		statement “In terms of exposure, many fish farms are situated in sea lochs or coastal waters that are protected from the rigours of the open sea; hence they are almost always in tidal zones such that sediment exposure to fish faeces deposition or other releases from the cages can occur both up- and down-gradient. This means that sediment exposure can occur in areas between cages and the shoreline, not just in areas between cages and the open sea.” [p17] is confused and meaningless, in relation to the well-characterised dispersion of particulate wastes from marine aquaculture sites. There is no evidence, or reasonable cause to expect, significant exposure of insects in intertidal sediments to emamectin residue originating from aquaculture. Inclusion of the Arenicola 10-day casting data is also dubious. CTT correctly question the derivation of the EC10 sub-lethal endpoint; a conclusion that “the results seem to indicate an effect is occurring” [p14] is not sufficiently robust to support the derivation of an EQS. In view of the above, the correct outcome of the CTT flowchart (Figure 1) should be a QS of 305 ng/kg (two MW amphipod datasets with AF of 100); noting that this does not account for more recently available datasets. If the Arenicola dataset is included, the AF should be 50; giving a similar QS of 258 ng/kg. CTT correctly conclude that the SEPA field study does not support a threshold for effects of emamectin. Re-analysis of the SEPA (2018) dataset shows that there is no basis to conclude that crustacea are more effected than other taxa; that there were uncontrolled habitat variables	 Noted. Noted.

		which preclude an unambiguous assessment of emamectin effects using GLMM or CCA; and that contrasting conclusions can be drawn from this dataset based on arbitrary inclusion of sites. Overall, it is surprising and concerning that both SEPA and UKTAG should derive recommendations of such consequence for the aquaculture industry, from such sparse and irrelevant datasets. The limited available data of ecological relevance, from two very similar corophiid amphipod species, supports a chronic sediment EQS of around 305 ng/kg (dry weight), so not significantly different to the previous EQS of 760 ng/kg wet weight, assuming sediment water content of 40-50%. The previous EQS should therefore be retained, pending review of the additional data recently provided by industry.	Thank you for the comment. Please see our response to the similar comment from Anderson Marine Surveys above.
Wester Ross Fisheries Ltd. in cooperation with Anderson Marine Ltd.	10	CTT appear to be uninformed of ongoing work undertaken by the industry, specifically to provide a wider range of test organisms relevant to the review. The CTT review and recommendation should have been delayed to take account of this additional data.	Please see our response to this comment from Anderson Marine Surveys.
Scottish Environment LINK	9	Scottish Environment LINK very much welcome the UKTAG review, which supports the conclusions of SEPA that Emamectin Benzoate has the potential to cause substantial harm in the marine environment and should be reduced. However, without further information we cannot support how the proposed EQS has been derived. Emamectin Benzoate can cause the mortality of a wide range of invertebrates – the extent to which this will impact the wider marine environment has not been fully	The proposed EQS is double the interim guidance supplied by SEPA because more chronic toxicity data in sediment dwelling organisms has become available since that position was set. These additional data mean a lower, less precautionary assessment factor is justified, although the same study has been used.

		identified – and LINK consider that a precautionary approach be taken, which may require the cessation of use of this substance or at least a substantial reduction in permissible EQS levels. LINK would like to see further information to clarify why the proposed acceptable levels of Emamectin Benzoate by UKTAG (23.5 ng/kg DW) are approximately double the interim guidance issued by SEPA (12 ng/kg DW)? We recognise that these levels remain substantially lower than previous EQS levels but consider it important that the disparity in the proposed EQS levels is justified. LINK is concerned that the available evidence suggests that the widespread Arenicola lugworm, a keystone species in soft sediments that provides vital structural services, is apparently the most sensitive to toxicity. We would therefore urge that a highly precautionary approach is taken to the EQS for this chemical in light of this evidence. We are also concerned that studies carried out by the industry to justify requests for a more lenient EQS have apparently been denied public access for reasons of commercial confidentiality. In particular, the industry recommendation that the EQS should be approximately 100 times higher (1290 ng/kg DW) than the interim guidance developed by SEPA and 56 times higher than the proposed UKTAG recommendation. We believe that this figure is simply not justifiable in view of the levels of toxicity and mortality already observed. We are also perturbed that Paragraph 6.9 indicates that further data resulting from more recent studies is expected to become available during the consultation period and will be taken into account. We would like clarification as to whether the further data referred to is the additional industry-funded study referred to in Paragraph 6.3 or another study. We	We should clarify that there are indications it is the most sensitive in the marine dataset. Currently the proposed EQS is based on chronic toxicity in a freshwater midge, which we believe is highly likely to be more sensitive to the chemical's mode of action, hence the proposed EQS should be protective of Arenicola. We note and understand your concern. Please see our response to the Coastal Communities Network.

		would request that, if the conclusions of this study are used to justify a revision and increase in EQS, a further full public consultation is undertaken. LINK consider that there is insufficient evidential data on the impact Emamectin Benzoate has on marine organisms and the wider environment for an accurate assessment on EQS to be made. We consider that it should be a prerequisite that all documentation of the scientific studies underpinning this review are made publicly available. Without access to these studies, LINK cannot support the proposed EQS.	
Scottish Environment LINK	10	No additional data.	
The Scottish Salmon Company	9	- SSC also does not find it appropriate to combine both freshwater and marine datasets to produce an overall marine EQS. - Using studies of freshwater insects to assess the impact of Emamectin benzoate on marine invertebrate communities is not appropriate due to the significant difference in their sensitivity to Emamectin. Datasets relating to these marine communities should be used rather than data sets relating to freshwater insects. - Additional marine and freshwater datasets should be analysed to allow for a better statistical comparison - SSC understands that previous studies submitted have not been used as driving datasets, instead used to alter the multiplying factor, we ask that these dataset are re-visited.	Thank you for the comment. Please see our response to Anderson Marine Surveys above and SSPO. Please see our response to the similar comment from Anderson Marine Surveys above in relation protection goals of a specific pollutant EQS. In relation to mode of action, we are further considering this in relation to FW vs marine organisms and seeking expert advice. We intend to do this as part of a revised proposal.

		- There is insufficient evidence to suggest that the midge species 'Clunio marinus' to which the study relates, is found in any locations on the west coast of Scotland in close proximity to fish farms. It is also noted that the species is associated with marine sediment, however its distribution is confined to the intertidal zone. As the presence of C.marinus is strictly limited in the intertidal zone, studies relating to this species should not be used to help inform and derive an EQS for marine sediment communities. To conclude we do not believe it is appropriate to use studies relating to freshwater insects to derive an EQS for marine sediment communities due to their significant difference in sensitivity to Emamectin. This argument is strengthened when considering there is no record of Clunio marinus to which the study relates in the Marine Recorder dictionary, suggesting there is no evidence that Clunio marinus is found around fish farm locations. We request that the derivation of the marine sediment EQS for Emamectin Benzoate is revisited using relevant marine datasets.	
The Scottish Salmon Company	10	No additional data.	
Scottish Sea Farms	9	Any proposed EQS should be applicable to the receiving environment and key sensitive species present. In the case of marine cage fish farming's use of Emamectin Benzoate, this should be limited to marine subtidal benthic and/or epifaunal organisms. We do not agree with the CTT's derivation including data on freshwater organisms where:	Please see our response to the similar comment from Anderson Marine Surveys above in relation to the protection goals of a specific pollutant EQS. In relation to mode of action, we are further considering this in relation to FW vs marine organisms and seeking expert advice.

		- the significant differences in apparent sensitivity indicate that data should not be pooled with marine species - they cannot be demonstrated as likely receptors for the regime being regulated - in the specific case of Clunio marinus, no distribution data is available which might suggest it to be present in the appropriate locations, or at risk, from marine farming activity. In 17 years' monitoring of marine fish farms I personally have no recollection of any Class Insecta species being recorded in either the vicinity of farm sites or at reference locations. A recent review of our 51 most recent monitoring surveys, including sites on the West Coast of Scotland from Argyll to Loch Eriboll, Orkney and Shetland, have also shown no record – see summary table below. see summary table below	Please see our response to SSPO. Please see our response to the similar comment from Loch Duart.

Survey Date	Site	Insecta present?	Clunio present?
11/01/2019	Eday	0	0
11/02/2019	Lismore East	0	0
21/01/2019	Lismore West	0	0
27/02/2019	Puldrite	0	0
12/11/2018	Spelve B	0	0
10/01/2018	Bloody Bay	0	0
04/04/2018	Bringhead	0	0
08/06/2018	Fishnish A	0	0
21/08/2018	Fishnish B	0	0
17/10/2018	Fiunary	0	0
19/02/2018	Nevis C	0	0

17/09/2018	Scallastle NW	0	0				
18/09/2018	Scallastle SE	0	0				
26/11/2018	Shapinsay	0	0				
04/09/2018	Tanera 2	0	0				
27/09/2018	Vidlin Outer	0	0				
04/04/2018	Westerbister	0	0				
02/11/2017	Camas Doun	0	0				
11/07/2017	Charlotte Bay	0	0				
08/02/2017	Creran B	0	0				
14/07/2017	Dubh Sgeir	0	0				
12/07/2017	Dunstaffnage	0	0				
21/03/2017	Eday	0	0				
23/06/2016	Fiunary	0	0				
21/06/2017	Kempie	0	0				
02/11/2017	Kishorn N	0	0				
05/10/2017	Kishorn W	0	0				
03/07/2017	Lismore West	0	0				
02/08/2017	Nevis A	0	0				
26/09/2017	Nevis B	0	0				
10/02/2016	Nevis C	0	0				
13/04/2017	Port na Moralachd	0	0				
16/09/2016	Scallastle SE	0	0				
16/09/2016	Scalastle NW	0	0				
15/11/2017	Shuna	0	0				
21/06/2017	Sian	0	0				
14/11/2017	Spelve A	0	0				
05/01/2017	Tanera 1	0	0				
05/01/2017	Tanera 2	0	0				
19/07/2017	Teisti Geo	0	0				
12/12/2017	Toyness	0	0				
28/03/2017	Lismore East	0	0				
16/05/2016	Bloody Bay	0	0				
02/11/2016	Fada	0	0				
05/07/2016	Fishnish A	0	0				
05/07/2016	Fishnish B	0	0				

		<table><tr><td>23/02/2016</td><td>Kishorn N</td><td>0</td><td>0</td></tr><tr><td>23/02/2016</td><td>Kishorn W</td><td>0</td><td>0</td></tr><tr><td>13/09/2016</td><td>Puldrite</td><td>0</td><td>0</td></tr><tr><td>16/09/2016</td><td>Scallastle NW</td><td>0</td><td>0</td></tr><tr><td>20/04/2016</td><td>Shapinsay</td><td>0</td><td>0</td></tr></table> We fully support the consultation response as provided by the SSPO and would ask that all points made therein are adequately considered by UKTAG. This should prompt a review of the CTT's recommended EQS to one which is relevant to, and appropriate for, the protection of marine subtidal species.	
Scottish Sea Farms	10	Please refer to SSPO response and attachments.	
Fish Vet Group	9	If the objective of the review is to "....derive the current EQS for the long-term protection of marine benthic fauna....." then the pooling of freshwater and saltwater data appears unjustified; specifically the Chironomid data should be viewed with caution, as fresh-water insects do not form part of the marine (subtidal) benthic invertebrate communities that may reasonably be considered to be impacted by aquaculture activities. In addition, the Arenicola 10-day casting data does not appear sufficiently robust to support the derivation of an EQS. Whilst protection of the marine environment is of paramount importance, revision of the sediment EQS appears to require further investigation and consideration of more pertinent trial results before any change to the standard can be proposed. In particular	Please see our response to the similar comment from Anderson Marine Surveys. Thank you for the comment. We agree with regard to the use of this study's sub-lethal endpoint. Thank you for your comment. We will consider mode of action and relative sensitivities further in our revised proposal.

		greater consideration should be given to the mode of action of emamectin benzoate on a range of invertebrate species that are likely to be directly affected (specifically those species on and within marine subtidal sediment) - where the influence of salinity, and differences in physiological responses of different marine invertebrate groups can be accounted for. The fate of Emamectin Benzoate residue in intertidal sediments may be very different to that encountered in the sub-tidal depositional zone that to date has been sampled and assessed, and a 'universal EQS' may not be appropriate. As the UKTAG proposals with regard to Emamectin Benzoate will have a significant impact on the aquaculture industry, the previous EQS should be retained until this additional and more applicable data has been considered, in order to inform any recommendation for a change in the Emamectin Benzoate sediment permissible residues limits.	Thank you for the comment. We will revise our proposal to include the new data. It is beyond UKTAG's remit to comment on regulatory aspects of standards, and what may be in use currently, as the substance does not have specific pollutant status currently.
Loch Duart Ltd.	9	As a farm operator we support the scientific scrutiny of environmental impacts, and welcome the process of Environmental Quality Standards reviews where all relevant and up to date information is taken into account and given appropriate weighting. With regards to the proposed Emamectin benzoate EQS we have concerns on several counts, namely: • Emamectin benzoate acts on GABA receptors relevant to invertebrate and vertebrate species, rather than the arthropod taxa focused on in the EQS derivation	Please see our response to the similar comment from Anderson Marine Surveys and SSPO above. In relation to mode of action, we are further considering this in

		assessment • A freshwater species has been used for derivation of a marine EQS; not only is this questionable in terms of relevant environmental fate of Emamectin benzoate, but given the mode of action of Emamectin benzoate on ion channels, the response of freshwater and marine species to Emamectin benzoate exposure will differ substantially Reviewing our own environmental monitoring data 2001 – 2019, totalling some 114 surveys around marine farm sites and associated reference stations, on no occasion have insect taxa been recorded. This, combined with the substantial differences inevitable in ecotoxicological response to Emamectin benzoate for marine and freshwater species and the single reference to the insect species Clunio around the intertidal zone on the west coast of Scotland, substantially challenges the way in which the proposed marine EQS has been arrived at.	relation to freshwater vs marine organisms and seeking expert advice. Thank you for this information. We presume the surveys were conducted to meet regulatory requirements and so would have been conducted in the sub-tidal zone for all stations, which would explain the absence of midge. In terms of species relevance and protection goals, please see our response to the first Anderson Marine Surveys comment.
Loch Duart Ltd.	10	We do not believe that all relevant information has been taken into account in derivation of the proposed EQS. The aquaculture and pharma industries have substantial amounts of information, including ecotoxicology data for a range of relevant test organisms and environmental monitoring data from the marine environment, which does not appear to have been taken into consideration As above, the aquaculture industry and pharma companies have relevant data relating to marine test organisms and environmental monitoring which should be taken into consideration. We believe that such information, as well as a review of suitability of the test organisms considered, must be taken into account before	We will revise our proposal to include the new data that has been highlighted to us as part of SSPO's submission.

		any further conclusions on Emamectin benzoate EQS are made.	

Detailed comments on emamectin benzoate EQS from SSPO – Table 1 **(Summary comments from SSPO that cover the main points have been addressed above. UKTAG have not repeated responses in this table, which is included to ensure all comments received are publicly available)**
Table 1. Background Report - Chemistry Task Team (CTT) recommendation for an EQS for emamectin benzoate.pdf: industry response *CTT Report statement – in italics* Response to statement – in body text
1 *SEPA use the concept of a "far field" and "near field" sediment EQS in their regulation of fish farms. The far field EQS is the situation covered by CIS 27, equivalent to an "annual average" water EQS (protective of chronic effects in sediment dwelling organisms on the basis that sediment exposure is likely to be long lived, especially in the case of persistent substances). It is used in regulation for compliance assessment. The near field EQS seems to be used in regulation as a trigger for additional far field monitoring requirements, and so could be thought of as more like a MAC (maximum acceptable concentration), although for the reasons stated MAC are less relevant for sediment exposures to substances of this kind. As this is a non-standard endpoint, CTT have focussed on the derivation of a sediment EQS in line with the principles of CIS 27.* We agree with this summary of the relevant roles of far-field and near-field sediment EQS for fish farming.
2 *There are not enough data to distinguish any differences in sensitivities between freshwater and marine sediment-dwelling organisms. As is the case for the pelagic data, CTT has followed CIS 27 guidance and pooled fresh- and saltwater data. This is further discussed below in relation to relevance.* This statement is incorrect, especially now that further studies are available. It is possible to compare any number of values, depending upon the underlying distributional assumptions that one is prepared to accept. Section A1.3.7.1 in CIS 27 provides a method for testing whether freshwater and marine datasets should be combined for EQS derivation. We can use this method to compare the data listed below:

- Freshwater sediment data:
  - o Log10 OC-normalised C. riparius NOEC value of 2.6 µg/kg dw = 0.415 µg/kg dw
  - o Log10 OC-normalised C. dilutus NOEC value of 4.8 µg/kg dw = 0.681 µg/kg dw
  - o Log10 OC-normalised H. azteca NOEC value of 43.2 µg/kg dw = 1.635 µg/kg dw

- Saltwater sediment data:
  - o Log10 OC-normalised L. plumulosus EC10 value of 492.87 µg/kg dw (based on geomean of two studies) = 2.693 µg/kg dw
  - o Log10 OC-normalised C. volutator value of 53.3 µg/kg dw = 1.727 µg/kg dw
  - o Log10 OC-normalised H. diversicolor value of 617.9 µg/kg dw = 2.791 µg/kg dw.

An F test to compare variance homogeneity between the freshwater and saltwater values, as required in CIS 27, produces an F statistic of 0.84 and a p value of 0.913. The variances of these two groups are therefore statistically similar and it is appropriate to continue with a two tailed t-test performed at a significance level of 0.05.

This t-test produces a t statistic of 2.97 and a p value of 0.041. The null hypothesis that the sensitivity of freshwater and saltwater sediment organisms is similar is therefore not supported and the two datasets should not be combined.

Available reliable and relevant dataset:

- *Marine: long-term toxicity in 2 crustacean species (3 studies in 2 copepod species); sub-lethal endpoint from acute toxicity study in a polychaete species (the lugworm Arenicola marina)*
- *Freshwater: long-term toxicity in 1 insect species*

This is no longer the most up to date list of available saltwater and freshwater sediment studies (see point 4 below)

The only reliable chronic sediment study available to WRc (2017) and subsequent peer review was the 28d emergence test with the freshwater midge Chironomus riparius. The peer reviewers agreed it was reasonable to use this freshwater study to derive a marine sediment EQS, following CIS 27 guidance. Since then three additional industry-generated chronic studies became available, two in the marine amphipod Leptocheirus plumulosus (EPP 2018e; EAG 2018) and one in the marine amphipod Corophium volutator (Scymaris 2018). In addition, the industry conducted an additional acute toxicity study in the lugworm Arenicola marina (EPP 2018c) and an acute toxicity study in the same Corophium amphipod species (EPP 2018d) as the chronic study. The chronic Corophium study included the more usual 28-day duration results but was also continued to day 75. The new studies all followed accepted international or national (US EPA)

guidelines except for the chronic Corophium study, the protocol for which was based on well document literature sources. Of the four available chronic studies, the most sensitive is the freshwater midge study (28 day NOEC 1.175 µg/kg dwt).

There is now an additional chronic study with the polychaete Hediste to add to the list of saltwater sediment tests, and two further freshwater sediment studies, with Hyalella and a second chironomid species, C. dilutus. Please see study summaries in Attachment 1.

The lowest overall sediment value remains the 28-day NOEC of 1.175 µg/kg dw for C. riparius. If this value is organic carbon normalised as required by CTT then it increases to 2.6 µg/kg dw (the organic carbon content of sediment used in the study was reported as 2.3%). In CTT's response to the industry EQS report there was criticism of industry for not normalising all sediment toxicity values to a standard sediment organic carbon content value of 5%. This criticism was related to the new studies commissioned by industry but, following this logic, the normalisation must also be completed for all other studies.
Interestingly, the OC-normalised NOEC of the second and newer chironomid study is slightly higher (4.8 µg/kg dw) than the one from the older study. This is surprising given the fact that the second study covered an extended exposure period (62 days versus 29 days), with a higher number of replicates (12 versus 4) and individuals (144 versus 80), and additional endpoints (including reproduction). Therefore, the second study is of greater relevance and should form the basis of any regulatory decision, as exemplified by the Environmental Protection Authority of New Zealand (2018), who use the NOEC from the second study as the relevant endpoint.

Considering the marine data in isolation, the sub-lethal endpoint in the new acute Arenicola lugworm study gave a lower result than those observed in the three marine chronic studies. This is a 10-day EC10 for casting of 12.9 µg/kg dwt (the lowest endpoint from the chronic studies is the geometric mean for the EC10 for growth rate from the two Leptocheirus studies, 30.5µg/kg dwt).

The Arenicola study produced a non-normalised casting EC10 of 12.9 µg/kg dw. However, in CTT's response to the industry EQS report there was criticism of industry for not normalising all sediment toxicity values to a standard sediment organic carbon content value of 5% (see Table 2 below).

If the Arenicola value of 12.9 µg/kg dw is organic carbon normalised in this way then the EC10 increases to 323 µg/kg dw. This is in the same range as the similarly normalised Leptocheirus growth EC10 492.87 µg/kg dw (based on the geomean of two studies) and the Hediste NOEC of 617.9 µg/kg dw, but contrasts with the normalised Corophium NOEC (all endpoints) of 53 µg/kg dw.

After the normalisation process recommended by CTT the most sensitive result from chronic saltwater sediment studies is therefore one obtained from a crustacean species, Corophium, with the lowest NOEC of 53 µg/kg dw. However, this NOEC is unbounded (it was the highest test concentration) and the true NOEC will therefore be higher.

CTT has reviewed the three additional chronic marine sediment studies and the two additional acute sediment studies and finds them all to be reliable and relevant, appropriate for use in hazard assessment and EQS derivation (see annex). However it should be noted that the sub-lethal endpoint from the acute Arenicola study has some shortcomings as it seems to be inherently linked to mortality, with this relationship having a greater impact at higher concentrations. The endpoint is based on the total number of casts, recorded daily in the 10-day test, but the decreasing number of animals in test concentration vessels is not taken into account in the statistical analysis. Reanalysis of the data to make this correction does not seem possible based on study design (i.e. not possible to count surviving worms at the same frequency as casts). Whilst the EC10 for casting (12.9 µg/kg) is lower than the NOEC for mortality (19.9 µg/kg), correcting for mortality would affect the slope and shape of the dose-response curve and so likely influence the casting summary statistic value. Nevertheless, the results seem to indicate an effect is occurring such that the results are not solely driven by the decreasing number of worms.

The "shortcomings" of the casting data in the Arenicola study are an unavoidable consequence of the design of this type of study with this organism (see more detailed response in Table 2, comment #9 below).
CTT's requirement for organic carbon normalisation means that this is no longer the most sensitive endpoint (see comment #5 above).

CTT also considered the available acute sediment toxicity dataset, because the lugworm result for mortality (LC50) indicated that the most sensitive species in acute studies may not have been tested in longterm studies. Reliable acute studies are available in:

- *Arenicola marina: 2 studies 10-day LC50s 111 µg/kg & 40.8 µg/kg*
- *Corophium volutator: 2 studies 10-day LC50s 193 µg/kg & 141 µg/kg*
- *The spot prawn Pandalus platyceros: 8d EC20 (mortality) 138 µg/kg*

It can be seen that the most sensitive species was the lugworm Arenicola marina, however two amphipod species have been used for chronic testing rather than this or a related species. Of these amphipod tests, the two Leptocheirus plumulosus chronic studies showed effects whereas the Corophium volutator did not. According to CIS 27 in the selection of assessment factors, chronic test data should cover the most sensitive species in the available acute studies.

The 95% confidence intervals for the studies mentioned by CTT are as follows:

- Arenicola marina: Two studies with 10-day LC50 values of 111 µg/kg ww and 40.8 µg/kg dw. The 95% confidence interval for the first of these studies (when wet weight is converted to dry weight, based on a moisture content of 28%) is 118 – 201 µg/kg dw. The 95% confidence interval for the second of these studies is 26 – 62 µg/kg dw.
- Corophium volutator: Two studies with 10-day LC50s of 193 µg/kg ww and 141 µg/kg dw. Probit models fitted to these data were unable to produce 95% confidence intervals. However, use of the simpler binomial method (Stephan 1977) produces the following LC50 and 95% confidence intervals for each study: 28 (0 – 578) (when wet weight is converted to dry weight, based on a moisture content of 28%) and 74 (12.9 – 420) µg/kg dw.

- The spot prawn Pandalus platyceros: 8d EC20 (mortality) of 138 µg/kg ww. There are no confidence intervals for this value because this is not a true EC20. There was 15% mortality at 0.1 mg/kg ww and 20% mortality at both 0.4 and 0.8 mg/kg ww in this study. However, there was only 2% mortality at both 1.2 and 4.8 mg/kg ww. Emamectin was therefore unlikely to have been responsible for the increased mortality at lower exposure concentrations due to a clear absence of a dose response relationship.

The 95% confidence intervals for Arenicola (26 to 201 µg/kg dw) and Corophium (0 to 578 µg/kg dw) overlap substantially which provides no evidence for a statistically significant difference in the acute sensitivity of the polychaete Arenicola and the amphipod Corophium.

The chronic data therefore do cover the most sensitive species in the available acute studies because there is no difference between the tested species.

The existing data set of marine studies is completed by a chronic study with the polychaete Hediste diversicolor which removes any earlier concerns that a chronic study was not available for the apparently most sensitive taxon in acute studies.

8

In deriving an EQS for sediment in this situation, there are three main factors to consider:

i. selection of the key study and endpoint depending on reliability and relevance; the key consideration in this case is the relevance of the freshwater midge data to the marine environment now that marine test data are available
ii. the appropriate assessment factor based on the completeness of the dataset and;
iii. how additional lines of evidence (e.g. field studies, acute dataset, investigated mode of action) affect the choice of assessment factor

In addition, for studies in sediment, it also needs to be considered whether normalisation of the data to a set organic carbon content fraction is appropriate both for comparison of studies and final EQS setting.
(Flow chart is included)

We agree with these statements.

i. Key data selection

As stated above, based on the lack of obvious differences in sensitivity in the freshwater and marine datasets, the WRc (2017) report and the peer reviewers of the report decided that pooling of freshwater and marine data was acceptable for pelagic EQS development in line with CIS 27 guidance (CTT agrees with this). Based on this decision and the lack of additional chronic data in sediment dwelling organisms, they also decided that the chronic freshwater midge emergence study was appropriate for sediment EQS development. CTT also agrees with this, but given the new studies in marine organisms an assessment of the relevance of freshwater insect species for the marine environment is necessary (note there are not enough data to assess relative sensitivities of freshwater and marine sediment dwellers).

The freshwater midge studies are not appropriate for the derivation of a saltwater sediment EQS. Statistical comparison of the freshwater sediment toxicity data, which includes the two midge values, with the saltwater sediment toxicity data (for crustaceans and polychaetes), using the CIS 27 methodology, shows that the midges are significantly different in their sensitivity to emamectin and should therefore not be pooled with the saltwater crustacean and polychaete data.

Although very rare, insects with interdidal/marine aquatic larval stages are known in the UK. According to Langton and Pinder (2007) in Britain there are almost 600 species of non-biting Chironomidae midge, in addition to 161 species of biting midges of the Ceratopogonidae family (Chandler 1998). Whilst the majority of these species inhabit freshwater rivers, streams and ditches as well as brackish water, the larvae of Clunio marinus inhabit fully marine waters, being most abundant in the mid-littoral zone. This species has been surveyed in the west of Scotland (O'Reilly 2008). Most of this species' life history is associated with the sediment, with adults emerging and reproducing in a matter of hours before both adult males and females die without feeding. Therefore insect data do seem relevant for the marine environment in this case.

The sole relevant reference to marine insects cited by CTT is to a paper by O'Reilly (2008). This is a one-page article published in The Glasgow Naturalist. In this article the author describes how: "During a warm, balmy, summer's evening on August 8th 2005, and again on

August 13th 2006, an excursion was made to the shore at Wemyss Bay, in the Firth of Clyde." On these excursions, O'Reilly noticed chironomids "dancing near rocks at the water's edge", caught a few of them, and identified them as Clunio marinus.
This interesting note by an enthusiastic naturalist does not constitute a "survey in the west of Scotland" as stated by CTT. No information on the wider distribution of Clunio is presented by CTT, so they have no way of knowing whether this single Scottish marine insect species occurs in any locations close to fish farms or, if it does, whether there is any evidence that it has been, or could be, adversely affected by exposure to emamectin.

The doubtful status of Clunio's presence in Scotland, including salmon farming areas, is highlighted by the following findings:

- Clunio marinus is listed both in the World Register of Marine Species (WORMS) and the Marine Species of the British Isles and Adjacent Seas (MSBIAS) subset. Consequently, Clunio marinus is included in the Marine Recorder dictionary. However, there are no records for Clunio marinus in the Marine Recorder.
- The NBN Atlas indicates four "Accepted" records (and no "Unaccepted" records) (https://species.nbnatlas.org/species/NBNSYS0000027483), but none of the records is at a location where salmon farming occurs (with one location being at Tarbat Ness at the Scottish East Coast).
- The Ocean Biogeographic Information System (OBIS) maps the taxon as present in the Clyde, but that system does not appear to have the ability to query the source of the record(s) concerned [https://obis.org/taxon/118146]. However, based on the general geographical location, this record most likely refers to the publication by O'Reilly (2008).

It is correct that most of this species' life history is associated with the marine sediment. However, it should be noted that its distribution is strictly limited to the intertidal zone (i.e., seabed that is covered and uncovered by the sea according to the rise and fall of the tide). Larvae move to the lower fringe of the eulittoral zone which is submerged at normal tides and is exposed only at springtides (Kaiser et al. 2011).

Further, given the inherently greater level of uncertainty in hazard assessment for the marine environment compared with the freshwater environment based on the greater number of (untested) taxa, a more precautionary approach can be justified. This is in keeping with the principles of CIS 27. In terms of exposure, many fish farms are situated in sea lochs or coastal waters that are protected from the rigours of the open sea; hence they are almost always in tidal zones such that sediment exposure to fish faeces deposition or other releases from the cages can occur both up- and down-gradient. This means that sediment exposure can occur in areas between cages and the shoreline, not just in areas between cages and the open sea.

CTT is incorrect to invoke the principle of "greater uncertainty" in hazard assessment for the marine environment in the case of emamectin. There is, in fact, a smaller degree of uncertainty in the hazard assessment of this substance when compared with a wide range of other substances released to the aquatic, and especially, marine environment. This is because the mode of action and target receptors for abamectins are specific and very well known, and there is an extensive sediment test database available for these specific target receptors and emamectin. Benthic taxonomic groups that were not tested, namely echinoderms and cnidaria, are likely to be less sensitive due to their lack of glutamate-gated chloride channels (Wolstenholme, 2012).

Based on these considerations CTT believes that the freshwater chironomid data are relevant for marine sediment EQS development.
If this is the case, then CTT must review every other saltwater EQS to ensure that marine insects are protected from exposure to all other substances. Under the Water Framework Directive Common Implementation Strategy this process would also need to be compatible with EQS derivation across all other Member States.

To the best of our knowledge this is the first time that CTT has expressed an interest in focusing a saltwater risk assessment on protecting insects. This interest has clearly only arisen because of the prior existence and use of freshwater sediment insect data. If CTT had been presented with only the saltwater sediment dataset for crustaceans and polychaetes then this would have exceeded the data requirements for setting a saltwater sediment EQS, and CTT would not have asked for any additional testing of freshwater sediment species.

Clunio marinus is cultured in laboratories for use in chronobiology studies and so could have been tested toxicologically if there had been any great desire on the part of regulators to focus an EQS on protecting this species. Instead, discussion between industry and regulatory authorities has been entirely about testing saltwater crustacean and polychaete species. At no point has industry ever been asked to test marine insect species and yet we are now potentially about to be regulated on this basis.
As the presence of Clunio marinus is strictly limited to the intertidal zone, freshwater insect data are not relevant for the derivation of a marine EQS if this EQS is meant to protect subtidal benthic faunal communities, or if this EQS forms the basis of a mandatory monitoring program in which sediment is collected only from the subtidal zone.

ii. Appropriate Assessment Factor

The available updated reliable and relevant chronic dataset includes studies in three species as follows:

- *28-day chronic toxicity to freshwater midge Chironomus riparius (WRc 2017)*
- *28-day chronic toxicity to the marine amphipod Leptocheirus plumulosus (EPP 2018e)*

- *28-day life cycle toxicity to the marine amphipod Leptocheirus plumulosus (EAG 2018)*
- *28/75-day chronic toxicity to the marine amphipod Corophium volutator (Scymaris 2018)*

This list of reliable and relevant studies can now be updated further, as detailed above.

In addition to these four studies in three species of arthropod, the 10-day acute toxicity to the lugworm Arenicola marina (EPP 2018c) study included a sub-lethal endpoint (EC10 for casting; see above discussion).
CIS 27 does not cover this exact situation. In table 5.3 CIS 27 provides guidance on the AFs to be applied depending on the dataset available:

- *"one long term freshwater and one saltwater sediment test representing different living and feeding conditions" leads to an assessment factor of 100;*
- *"three long term sediment tests with species representing different living and feed conditions" gives an assessment factor of 50 and*
- *"three long term tests with species representing different living and feeding conditions including a minimum of two tests with marine species" leads to an assessment factor of 10.*

The guidance to marine sediment assessment factors in general also states:
"The general principles of notes (c) and (d) as applied to data on aquatic organisms (Table 3.3) shall also apply to sediment data. Additionally, where there is convincing evidence that the sensitivity of marine organisms is adequately covered by that available from freshwater species, the assessment factors used for freshwater sediment data may be applied. Such evidence may include data from long term testing of freshwater and marine aquatic organisms, and must include data on specific marine taxa."
Despite the presence of an additional marine species, because this does not seem to represent a significantly different living and feeding condition, the "default" position would be to apply an assessment factor of 100 to the chironomid data, on the basis that the life history of the midge is significantly different to that of the marine amphipods (ie "different living and feeding conditions"). However, based on the increased confidence the additional study gives for toxicity in this taxa, the supporting sub-lethal effects data from the acute Arenicola study, and the fact that the freshwater data represent a taxa known to be sensitive to the substance's mode of action, in keeping with the "general principles" guidance note above CTT believes that an assessment factor of 50 can be applied when considering the laboratory data in isolation.

CIS 27 Table 5.3 specifies an assessment factor of 10 if there are "three long term tests with species representing different living and feeding conditions including a minimum of two tests with marine species." These conditions are met by the available dataset in which the

following four long-term sediment tests are available for crustacean and polychaete species with different living and feeding conditions, including three tests for marine species:

- Leptocheirus: burrowing surface deposit-feeding amphipod (Bridges et al 2017)
- Corophium: burrowing suspension and surface deposit-feeding amphipod (Gerdol & Hughes 1994)
- Hediste: burrowing predatory and scavenging polychaete (Costa et al. 2006)
- Hyalella: epibenthic grazer and surface deposit-feeding amphipod (Strong 1972).

iii. Additional lines of evidence

Additional lines of evidence can be used to modify assessment factors recommended for laboratory data through expert judgement. As described in the CIS 27 guidance, key information can relate to field studies. Peer reviewers of WRc (2017) also recommended QS development based on acute toxicity testing, either through the assessment factor approach using sediment dweller data or equilibrium partitioning approach using pelagic data, as further lines of evidence for choice of chronic data assessment factor. CIS 27 describes these approaches, in particular in relation to situations where no chronic data are available. Applying the assessment factor (deterministic) approach to the acute toxicity dataset available now would lead to a QS for sediment of 41 ng/kg dwt (rounded) based on the 10-day LC50 of 40.8 µg/kg in the lugworm (Arenicola). However CTT believes these are poor additional lines of evidence to inform choice of assessment factor for chronic data, since both are inherently less certain than chronic data; both approaches are often used to "drive" the need for chronic testing in risk assessment. The mode of action of emamectin benzoate appears to have been well studied, although a later publication appears to indicate it may be relevant for a wider range of species and taxa than thought previously (see Uses of the Substance section).

We agree with CTT that chronic laboratory sediment data are more relevant than acute data and equilibrium partitioning modelling when deriving a sediment EQS, especially when the dataset is extensive, reliable, and consistent.

The best pieces of additional evidence that can be considered in relation to choice of assessment factor are the two field studies. Unlike laboratory toxicity data, such studies are usually high in relevance but low in confidence. Based on the results of statistical analysis for the SEPA study (SEPA 2018), no threshold for effects can easily be derived from these data. However the SEPA field study suggests that a concentration somewhere in the region 10 – 100 ng/kg dwt should be protective of impacts on macroinvertebrate abundance/diversity of benthic fauna. The industry-led field study gave quite different results, based in part CTT believes on the differences in study design (lower density of sampling points) and the way emamectin concentration ranges and species presence happened to fall in the analysed samples.

Various statistical approaches were applied to the data, since initial analysis of the total dataset seemed to indicate a toxicologically implausible correlation between emamectin concentrations and species richness. Truncation of the concentration data allowed an investigation of the impact of concentrations in ranges representative of proposed EQS (see description of study). CTT believes the findings of the survey are equivocal because of the inherent differences in populations in samples, the noise in the data and lack of granularity in the sampling regime. Taking the results of both studies into account, CTT does not see a clear line of evidence that would enable a relaxing of the proposed assessment factor of 50, as discussed above.

We agree that reliable field data should be considered as an additional line of evidence when setting an EQS.
CIS 27 (p 28) states that "Given the variability in field data (and indeed in laboratory ecotoxicity data), small differences between a laboratory-based QS and field data should not be given undue weight. We suggest that differences larger than an order of magnitude would, however, warrant further investigation and, if justified, a revision of the AF."

CTT currently recommends a saltwater sediment EQS of 23.5 ng/kg dw, so if field effects were evident only at concentrations above approximately 235 ng/kg dw then this should warrant further investigation and possible revision of the assessment factor.
We agree that field data from both the SEPA and PFMS studies provided toxicologically implausible results at very low concentrations. However, the data also show that when these anomalous data are removed there is no evidence to suggest that emamectin concentrations up to approximately 1 µg/kg ww would adversely affect crustacean populations. Interestingly, this is similar to the concentration at which no effects are observed in the most sensitive sediment test (C. riparius).
An EQS of approximately 1 µg/kg dw is therefore safe for the environment, as shown by both laboratory and field studies. This value is considerably more than an order of magnitude greater than the EQS proposed by CTT, so the size of the assessment factor should be reviewed (see comment #16).

16

Normalisation to a set organic carbon content (5% recommended in CIS 27): the freshwater chironomid study OC content was 4.5%. Because this content is close to the CIS27 guidance and the field study data show that sediment OC can vary greatly with distance from cage edge and tidal currents, CTT has not normalised the recommended sediment EQS to 5% OC.
Based on the currently available data and the considerations described above, CTT recommends applying an assessment factor of 50 to the chironomid data giving a sediment EQS of 23.5 ng/kg dwt.

If CTT requires normalisation of sediment data to an organic carbon content of 5% then it makes sense for this to be done for all data to minimise residual error. Normalisation of the C. riparius NOEC produces a value of 2.6 µg/kg dw (see comment #4).

As discussed above, we strongly disagree with the use of the C. riparius data with an AF of 50 because the relevance of the former remains unproven and the latter is far too high. Neither of these values is consistent with CIS 27 guidance.

We would support the derivation of a saltwater sediment EQS based upon the most sensitive saltwater sediment value (organic carbon normalised Corophium NOEC of 53.3 µg/kg dw) and an AF of 10, which produces an EQS (rounded down) of 5 µg/kg dw.
However, evidence from field studies should be taken into account when setting an EQS and these studies demonstrate safety below a concentration in the region of 1 µg/kg ww, with less certainty above this concentration. We therefore propose that for additional safety an AF of 50 is applied to the Corophium NOEC and the value is then rounded down to an EQS of 1 µg/kg dw. This value is lower than the NOEC for the most sensitive freshwater species that has been tested (C. riparius) and would therefore also protect this species.

"near field" sediment EQS
This derivation is not covered by CIS 27, as described at the start of this section. CTT have not proposed a value for this endpoint. Although the near field EQS is described as being used to trigger additional monitoring in the far field for compliance assessment by SEPA, it is not clear how assessment factors, and so the relationship between the near field and far field EQS, were decided in derivation of the SEPA 1999 standards for which there is a factor of ten difference. In any case it is likely that relationships between "Allowable Zone of Effect" (ie the seabed area immediately impacted in a fish farm cage) concentrations and the "far field" EQS compliance will vary from farm to farm depending on specific issues related to the farm itself and environmental factors of the local area, many of which could be modelled. This adds complexity in that it seems likely that a single "near field" EQS that will ensure at all farms on the one hand adequate far field protection and on the other avoidance of wasted resources in unnecessary additional monitoring is challenging.

The original SEPA 1999 derivation used an assessment factor 10 times lower than that for the far field EQS. This appears a defensible approach for this non-standard endpoint, as it seems to represent a commonly accepted acute:chronic toxicity ratio if the "near field" EQS is considered a surrogate for a MAC.

We agree that derivation of a near-field EQS is beyond the remit of this exercise.

Detailed comments from SSPO – Table 2 (responses to UKTAG's comments on industry EQS derivation that was submitted as part of the data package. Documented here so that they are publicly available)

Table 2. Background Report – Chemistry Task Team (CTT) comments on 2018 industry sponsored EQS derivation report for emamectin benzoate.pdf

UKTAG Background Report on Industry EQS derivation statement - italics
Response to UKTAG report statement – body text

1

UKTAG report statement: wca Environment did not carry out an evaluation of the reliability and relevance of the pre-existing ecotoxicity data, instead relying on the reliability stated in the 2017 WRc report (WRc 2017; this is relevant for the pelagic derivations).

SSPO response: This statement is correct. wca generally accepted that the ecotoxicity data applied in the WRc EQS derivations for emamectin benzoate had already been evaluated for reliability and relevance (by WRc or others previously) and that the reliability and relevance of this data had been accepted by SEPA, since the WRc EQS report was sponsored by SEPA and is published and available in the public domain. However, it does appear that this assumption was incorrect and that some of the data presented in the WRc report remained equivocal. Such equivocality was thus carried over into the wca report, where the same data were utilised. The primary objectives of the wca report were to take the previous EQS assessment (WRc 2017), and to update it to include the new marine sediment data that had been generated by industry in 2018. As such, wca did not undertake any specific evaluation of the WRc report itself, nor did we conduct any new searches of the published literature to assess if there are further ecotoxicity data on emamectin (either not identified by WRc or published since the WRc report was drafted).

2

UKTAG report statement: Based on the recent mysid shrimp study (EPP 2018a) and the existing acute mysid shrimp studies, wca environment derived a geometric mean of the three LC50s to give the MAC-QSpelagic. As discussed in the Chemistry Task Team Recommendation for an EQS for Emamectin Benzoate document, CTT does not think the original mysid shrimp studies are reliable (and may in fact be the same study, a point that is relevant for geometric mean derivation).' AND 'wca environment did not consider additional data in the dataset that could allow a lowering of the assessment factor, hence the difference in assessment factor from

that used in the CTT recommendation. This may have been because they took not only the reliability assessment but also the assessment factor selection in the 2017 WRc report as being agreed.
SSPO response: As noted in the response to 1. above, wca did not undertake any detailed evaluation of the WRc EQS report, nor of the data applied by WRc to derive the EQS. wca generally accepted that the ecotoxicity data applied in the WRc EQS derivations for emamectin had already been evaluated for reliability and relevance (by WRc or others previously) and that the reliability and relevance of these data had been accepted by SEPA, since the WRc EQS report was sponsored by SEPA and is published and available in the public domain. As such, wca did not undertake any specific evaluation of the WRc report itself, nor did we conduct any new searches of the published literature to assess if there are further ecotoxicity data on emamectin (either not identified by WRc or published since the WRc report was drafted).

Thus, both the reliability assessment carried out by WRc and the assessment factor applied by WRc in the derivation of the MAC were also considered to be accepted (at least by SEPA). Since the only new acute pelagic ecotoxicity data generated in the industry-sponsored 2018 testing programme for emamectin was for a species already represented in the dataset (mysid shrimp), it was considered that the 'agreed' AF would not be altered. However, it appears that the existing mysid shrimp data are considered by CTT to be unreliable, despite their use by the US EPA in regulatory assessments for emamectin, and that CTT believe that some of the other existing acute invertebrate data could be applied to reduce the assessment factor. We have not been able to review the original mysid shrimp studies (or study), but would accept the arguments made by CTT with respect to its potential reliability, and since a new test for this species has now been undertaken by industry, the original data can be discarded in the MAC derivation.
We would also agree that the additional acute crustacean datum is sufficient to allow a reduction of the AF.

3

UKTAG report statement: The value wca used for the new study also differs from that used in the CTT recommendation. wca used a value of 0.112 µg/l as opposed to 0.078 µg/l. This value is not reported for the 96h LC50 in the study report and does not correspond to nominal concentrations. It may be the LC50 for 72 hours' exposure.
SSPO response: We agree that the correct value to be used in the MAC derivation is the 96-hour LC50 for mysid shrimp of 0.078 µg/L. The value applied in the industry-sponsored EQS report was indeed the 72-hour LC50 and was used in error.

4

UKTAG report statement: Both recommendations use the same datapoint from the new mysid shrimp study. However wca environment used a non-standard assessment factor of 20, as was used in the WRc 2017 report. Again this may have been because they took not only the reliability assessment but also the assessment factor selection in the 2017 WRc report as being agreed.

SSPO response: As noted in responses to 1. and 2., above, it was assumed that the AFs recommended by WRc had been accepted by the regulators, and since the new data did not add anything in terms of additional taxonomic groups or feeding strategies, the same AF was applied in our assessment.
We accept, however, that based on a full analysis of the available chronic pelagic ecotoxicity data for emamectin, an AF of 50 is more appropriate in the derivation of an AA-EQS.

5

UKTAG report statement: In addition to the full laboratory test dataset, wca also considered the results of the industry field study in their derivation. It is not clear whether they were asked to consider the SEPA field study (SEPA 2018).

SSPO response: The SEPA-sponsored field study on emamectin was not considered in the industry-sponsored EQS derivation as the full results were not available to us at the time the EQS report was drafted.

While the SEPA field-study report itself was available, there appeared to be numerous omissions in the monitoring data utilised in the assessment and the statistical approaches applied. SEPA responded to an FOI request from industry for specific data to support their field assessment by sending a large volume of (mostly irrelevant) information. Owing to the need to carry out a detailed screening of this data package, it was not possible to conclude our evaluation of the SEPA field study in a suitable time period to allow its inclusion in the industry-sponsored EQS report.

UKTAG report statement: In their summary of the chronic Leptocheirus data, wca presented an EC10 (growth) of 17.6µg/kg for the EPP 2018e study as the most sensitive endpoint in truly chronic studies. However this result is not presented in the study report, instead a NOEC of <21.7µg/kg (the lowest concentration tested) is presented alongside an EC50 of 65.6 µg/kg (95% confidence intervals 58.9, 74.2) for the endpoint (the report did not present EC10s for any endpoints, just NOECs, LOECs and EC50s). CTT can agree with the EC10 value as presented by wca as the most sensitive endpoint in this study (and the more sensitive between this and the EAG 2018 study).
SSPO response: The EC10 was calculated for this study after production of the final test report at the request of wca, since the reported (censored) NOEC value has limited utility in EQS derivation. The statistics for calculation of the EC10 were provided to the study monitors in a separate 'non-GLP' supplementary report. This should have been supplied to CTT with the original test report but was omitted in error.

7

UKTAG report statement: CTT thinks wca environment's approach to combining EC10 growth results from the two Leptocheirus studies, as the most sensitive endpoint for this species in both studies, is incorrect, as follows. The EAG 2018 study derived an EC10 for

growth for males and females separately, whereas the EPP 2018e study did not consider sexes separately. However wca have taken a geometric mean of the three results (i. EC10 for growth (males) and ii. EC10 for growth (females) from the EAG 2018 study, iii. derived EC10 for growth EPP 2018e study), in effect treating them as if they are from three different studies, not two. Although CIS 27 guidance recommends the use of the geometric mean to combine results from multiple studies, the guidance does not specify what to do when combining results within a study. CTT believes an average of the male and female growth rates in the EAG 2018 study must first be taken, then a geometric mean of the two studies derived. Using either the geometric or arithmetic mean gives a mean EC10 (growth) for the EAG 2018 study of 53µg/kg, and so a geometric mean for the species/endpoint (17.6 and 53µg/kg) of 30.5µg/kg, as opposed to 36.6 µg/kg as presented by wca.

SSPO response: As noted by CTT in their statement, the CIS 27 guidance does not specify what approach to take when combining results within a study. While we acknowledge the points made by CTT in this respect, we do not necessarily agree that is erroneous to take a geometric mean of all three results in this case. However, we did undertake both approaches in our assessment and the outcomes were compared (but not included in the industry-sponsored EQS report).

The difference between 30.5 and 36.6 µg/kg was considered negligible in ecotoxicological terms (i.e. likely to be well within the inherent variability of the testing process), and therefore we elected to apply the slightly lower value. In addition, the selection of one value over the other has no overall effect on the subsequent EQS derivation.

8

UKTAG report statement: Of the four available chronic studies, the most sensitive is the freshwater midge study. However, wca discounted this study as not relevant. They state:

"The data derived for marine species significantly expands the available reliable data for EMB (emamectin benzoate) ecotoxicity to benthic organisms and they are sufficient to derive a marine sediment EQS without the need to include the freshwater (C. riparius) data. The larvae of C. riparius live and feed in freshwater sediments, but adults are not aquatic. In addition, the most sensitive endpoint in the C. riparius study was adult emergence from pupae (i.e. following metamorphosis from larvae). There are no truly marine insect species. From the 25,000-30,000 insect species that are aquatic or have aquatic larval stages, only a fraction, perhaps several hundred species, are marine or intertidal (Cheng 1976). Their habitat is limited to transitional environments provided by estuaries, saltmarshes, mangrove swamps, and the intertidal zones (Cheng 1976). Furthermore, since there are no marine invertebrate species which have life cycles involving aquatic larvae and non-aquatic adults, this study could be considered as not relevant for the

derivation of a long-term marine sediment EQS for EMB. We have therefore derived a sediment EQS for EMB using only marine sediment data."

CTT does not agree with this conclusion, as there are valid reasons for using the freshwater midge study (see CTT's sediment EQS recommendation in the Chemistry Task Team Recommendation for an EQS for Emamectin Benzoate document).

SSPO response: While relevance is not addressed specifically in CIS 27, the guidance document does propose the use of the CRED study reliability and relevance approach for assessing if individual studies are both reliable and relevant for EQS derivation. For a study to be relevant in this context it would be expected that the species and endpoints are directly applicable to the protection goal being sought. In this case, the protection goal is marine species, so the use of a freshwater species to derive the EQS is clearly of questionable relevance.
As stated in the industry-sponsored EQS report, we acknowledge that there are a small number of intertidal insect species, and accept that Clunio marinus has been observed on the Scottish coast (but see the limitations pf these observations noted in Table 1, comment #10). However, intertidal cannot be considered as fully marine in biological terms, and the fact remains that there are no truly marine species with benthic larval stages which metamorphose into non-aquatic adults. The freshwater insect emergence endpoint is therefore clearly not relevant to truly marine species – i.e. those that are likely naturally to occur in the vicinity of fish farms and therefore be exposed to emamectin.

Intertidal species, and specifically insects, have not previously been stated as a protection goal for the emamectin EQS, and we have no knowledge of any requirement for intertidal sediment sampling for mandatory routine monitoring of fish farm medicines. Furthermore, if the freshwater insect data did not exist, the EQS would be derived according to the available marine sediment ecotoxicity data, and according to the approach prescribed in CIS 27. There would be no requirement to generate 'marine insect' data for this purpose, and 'marine insects' would not be considered to be a data gap in this respect (nor are 'marine insects' mentioned as an 'additional marine group' for marine EQS derivation in CIS 27, which would be expected to be the case if they were an important marine group requiring protection from exposure to substances).

9

UKTAG report statement: In their derivation wca did not comment on the relative sensitivities of marine benthic organisms in the available acute toxicity dataset. Reliable studies are available in:
• Arenicola marina: 2 studies 10-day LC50s 111µg/kg & 40.8µg/kg
• Corophium volutator: 2 studies 10-day LC50s 193µg/kg & 141 µg/kg1

• *The spot prawn Pandalus platyceros: 8d EC20 (mortality) 38µg/kg*
It can be see that the most sensitive species was Arenicola (wca used the sub-lethal casting endpoint in as the key datum in their derivation), however two amphipod species were chosen in the first instance for chronic testing rather than an annelid. This means the current chronic dataset does not represent known sensitive species.

SSPO response: The values quoted do not represent absolute measures of toxicity to a species, but merely a statistical estimate of the concentration affecting 50% of species (in single ecotoxicity tests) which, like all statistical estimates, require a measure of variability in the form of confidence limits. The confidence limits associated with the LC50s listed above (Table 1, Comment 7) have not been taken into account by CTT in the assessment of the relative sensitivities of these species, although there is substantial overlap in them. Therefore, it is not possible to say whether any of the tested species is more acutely sensitive, based on these studies alone. In addition, the approach taken with respect to the new sediment testing programme was discussed with SEPA before the commission of any of the new studies. At no point was it suggested that a chronic Arenicola/polychaete study should be undertaken based on the apparent relative acute toxicity of different marine species (nor, indeed, was the requirement for an insect study ever mentioned). Furthermore, it is not clear what form of chronic annelid study the CTT statement suggests should have been undertaken, nor what specific endpoints CTT would have expected to be investigated. There are no standardised guidelines for an extended Arenicola sediment test (beyond the casting measurement within a 10-day test), and in our experience such studies are not possible without the addition of food, which needs to be mixed into the sediment. This process itself disturbs the worms (effectively meaning that worms must be transferred to new sediment mid-study) and usually fails to provide valid results.

Once it became apparent to industry that Arenicola might be particularly sensitive to emamectin (casting endpoint in the new 10-day test), a further study using a standardised polychaete methodology was commissioned. Hediste has a different feeding strategy to Arenicola, but we considered that, on balance, use of a standardised methodology was preferable to a non-standard extended Arenicola study with potential test validity issues. With the conduct of the Hediste study, CTT's request "…for chronic testing rather than this [Arenicola] or a related species" is fulfilled.

Finally, please see further comments below regarding adjustment of the new marine sediment studies for Organic Carbon (OC) content (also see Table 1, Comment 5).

10

UKTAG report statement: However, they did not discuss how the EC10 for casting was derived and the fact that it appears the study authors did not take into account the decreasing number of worms per test vessel in statistical analysis for the endpoint (see discussion in CTT sediment EQS section in the Chemistry Task Team Recommendation for an EQS for Emamectin Benzoate document).
SSPO response: It is not possible to separate mortality and casting in the 10-day Arenicola study. The two endpoints are inherently linked, simply because mortality can only be assessed at the end of the test (i.e. at 10 days) because the soft bodies of dead worms tend to disintegrate completely. Mortality is assessed by counting remaining live worms after 10 days. To attempt to assess mortality at earlier time points would risk damaging the remaining live worms and therefore invalidating the test. We acknowledged in our report that the casting endpoint as measured in a short-term (10-day) Arenicola test is not the ideal endpoint to utilise in deriving the sediment EQS. However, since it was measured in the study and it transpired to be the lowest 'no effect' value in the marine sediment dataset existing at this date (prior to OC adjustment), we considered that it should be applied in the derivation. However, we recognised the deficiencies in this approach, and therefore immediately commissioned a new polychaete study to address this uncertainty.

UKTAG report statement: wca environment go on to describe the ongoing conduct of an additional chronic study in the polycheate Hediste diversicolor (the European ragworm) to address this deficiency. What they do not do is adjust the assessment factor, the lowest available according to CIS 27 for the deterministic approach to deriving EQS, to account for this uncertainty in their derivation.
SSPO response: The uncertainty in the derivation inferred by use of the endpoint from the 10-day Arenicola test was addressed by conducting a new long-term polychaete study. The results of this were not available when the industry-sponsored EQS report was drafted. There was therefore no need to account for this uncertainty in the AF since the polychaete study added a further marine group and feeding strategy to the assessment.

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UKTAG report statement: In their derivation, wca have not normalised results relative to a standard organic carbon content as is recommended in CIS 27. Most of the new toxicity studies have very low OC contents; at 0.2 to 0.3%, more than ten times lower than the CIS 27 standard (the chronic Corophium study (Scymaris 2018) is far higher, at 5.75% OC). The Arenicola study wca used for their EQS derivation had an OC content of 0.2%, far from the standard content recommended by CIS 27.

SSPO response: We accept that CIS 27 recommends normalising sediment ecotoxicity studies to a standard organic carbon content. This was not performed because the OC content of the studies carried out by EPP was very low – as noted by CTT in their response – and to do so would have significantly increased the derived toxicity thresholds.

Our assessment was therefore based on an honest attempt to highlight a 'worst case' in terms of toxicity, accepting that if the test sediments had contained more OC, the results would likely have shown significantly lower sensitivity.
Nevertheless, since CTT have highlighted this deficiency in our assessment, we have re-analysed the results and normalised them to the standard OC content recommended by CIS 27. Based on this assessment, the Arenicola EC10 increases to 323 µg/kg dw, the Leptocheirus growth EC10 to 492.87 µg/kg dw (based on geomean of two studies)and the Corophium NOEC (all endpoints) decreases to 53 µg/kg dw.

UKTAG report statement: wca environment also provided a critique of the industry-sponsored field monitoring study (SAMS 2018), stating that it is of limited use in setting an EQS because no dose-response relationship was apparent between emamectin concentrations and measures of benthic impact (the key one being crustacean richness), even though various statistical approaches were followed in interpreting the data. They go on to state that the study is still useful because they believe it supports their far field EQS derivation precisely because no dose/response relationship was derived for concentrations within the concentration range that includes their proposed EQS (ie they deem their EQS proposal a protective, "responsible" value). CTT agree with their explanation of the study's result but interpret the study's shortcomings as being a strong reason for not "proving" the absence of effects, contrary to wca environment's conclusion.

SSPO response: This is not 'wca environment's conclusion', but the conclusion of the report on the field monitoring study itself. It was merely included in the industry-sponsored assessment so that all industry work in supporting the EQS development for emamectin was included.

UKTAG report statement: wca's sediment EQS development uses the lowest possible assessment factor for the deterministic approach, despite their recognition of some of the shortcomings in the dataset (EQS based on a sub- lethal endpoint from an acute study of short duration). Derivation should take account of the uncertainty with the key data through assessment factor selection; in this case that would mean deciding to use a higher assessment factor than the lowest permitted according to CIS 27.

SSPO response: In the industry-sponsored EQS report, we attempted to recognise and address the deficiencies and uncertainties in the available marine sediment dataset. The main uncertainties highlighted by CTT appear to be focussed on Arenicola being the most acutely sensitive marine sediment organism, and the lack of a long-term datapoint for Arenicola (or a related species).
As shown in our responses above, it is now clear (following adjustment for OC content) that polychaete worms are not the most sensitive taxonomic group to emamectin. Nevertheless, even when considering the unadjusted acute and chronic marine sediment

ecotoxicity values, the assumption by CTT that Arenicola had already been shown to be the most acutely sensitive species is flawed because it does not take account of the variability inherent in the results of single ecotoxicity tests.

Having completed the new marine sediment ecotoxicity testing programme, it became apparent that the (unadjusted for OC) sub-lethal casting endpoint in the acute Arenicola test was the lowest threshold value in the marine sediment dataset. This uncertainty was addressed by immediately performing a new long-term polychaete study, which (although results were not yet available for the EQS report) was mentioned in the report as 'to follow' and we believe therefore allowed a lower assessment factor to be selected than would otherwise have been the case.

CTT also highlight that the SEPA-sponsored field study was not included in the EQS assessment. The SEPA study was not included in the EQS assessment because the reported results were considered to be less conclusive than the industry-sponsored study, and the application of a range of multivariate and generalised modelling statistical analyses to try to demonstrate the effects of toxicologically implausible emamectin concentrations required significant additional assessment by industry to evaluate their validity. This assessment required us to request additional information from SEPA, and these data were not provided in a manner that made assessment quick or easy. Overall, while it is true that SEPA themselves highlighted some alternative findings to the industry sponsored field study in their field study on emamectin, it is clear that their study shows equally inconclusive outcomes when attempting to relate emamectin concentrations to the presence or absence of particular marine species.

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Annex B – List of respondents

Organisation
Anderson Marine Surveys Ltd.
Anglian Water
Biotikos Ltd.
Coal Authority
Coastal Communities Network (Aquaculture sub-group)
David Nattress
Energy UK
Environment Agency (Cumbria and Lancashire Area)
Fish Vet Group
Guernsey Sea Farms Ltd.
Inland Waterways Association
Loch Duart Ltd.
Mowi Scotland Ltd.
National Parks Wales
National Trust for Scotland
NFU
Northern Ireland Environment Agency, on behalf of Ecoregion 17 Alien Species Group
Northumberland Inshore Fisheries and Conservation Authority
Scottish Environment LINK
Scottish Sea Farms
Scottish Water
SSE
Scottish Salmon Producers Organisation (SSPO)
Stantec
Thames Water Utilities
The Scottish Salmon Company
Ulster Angling Federation
United Utilities
Warwickshire County Council (Flood Risk Management)
Wester Ross Fisheries Ltd. in cooperation with Anderson Marine Ltd.
Yorkshire Water Services