FK2

From: Storm, Debbie
Sent: 27 October 2015 13:12
To: MacNaught, Kevin; Wells, Mark
Subject: RE: Update on Aquaculture - SLICE issue
Sensitivity: Confidential

I think the three of us need to get our heads together on this one. Alarm bells going off all over the place!

FR-1

From: MacNaught, Kevin
Sent: 27 October 2015 12:31
To: Storm, Debbie; Wells, Mark
Subject: Update on Aquaculture - SLICE issue
Sensitivity: Confidential

Hi, I've had a chat with Hazel today about the SLICE issue and this is the current situation -

- Andy Rosie has changed his position on this yesterday.
- He no longer wants to rely on the outcomes of the Post-Authorisation Monitoring Project (PAMP) report as it is still in draft.
- They think the PAMP report won't be published for another couple of months.
- We're no longer looking at withdrawing SLICE completely.
- Use of SLICE was authorised by SEPA on the presumption that it would be used once or twice a year but we're seeing much greater use. Double-dosing is happening which wasn't what SEPA authorised.
- Current thought is that SLICE can be used for the current cycle – i.e. SLICE can be used on fish currently in the water.
- But a partial suspension would be issued on SLICE after this.
- This issue apparently hasn't gone to AMT yet. However Andy has apparently been in touch with Marine Scotland about it.

I sent over Qs for a Q&A so she is drafting some answers to these.

Cheers,

Kevin

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Mackinnon, Alison

FR9

From: MacNaught, Kevin
Sent: 29 March 2016 12:01
To: Wells, Mark
Subject: FW: PAMP Report - update info

Fyi

FR8

From: Sinclair, Douglas
Sent: 25 March 2016 16:21
To: Storm, Debbie; Baird, Stuart
Cc: MacNaught, Kevin; Rosie, Andy; Gritten, Barbara; Montague, Michael; Davies, Janet
Subject: RE: PAMP Report - update info

Hi folks

Just to provide you with an update on the state of play as concerns this report/study.

At the time of the last exchange of e-mails Directors were "voting" on whether the report should, or should not, be published. The conclusion was a conditional yes with most Directors thinking the report should be published but expressing various reservations. The SARF Chair then therefore suggested that they seek a suitably qualified person to look at the work and produce a "Moderation Report" – no, I don't know what that is either. It has become clearer however that this is essentially just another referring step, a cynic (who? Moi?), might say just an attempt to find reasons not to publish. The report is already I think the most heavily referred report in SARF's history, maybe even in the history of published science – 9 referees reports in two separate rounds.....though admittedly, 6 of those reports were not really from referees but consultants paid for by the drug company whose product (Slice) is implicated in the research work.

Upshot is that this Moderator has to produce a "final or progress report" by the SARF Board meeting which is on the 12th May, meaning that the final report on the PAMP study won't be published before that date.

By May of course the growing season will be well underway and there will be lots of long grass around....

All the best

D

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I no longer work on Mondays, normally available Tuesday - Friday.

During absences from the office, my e-mails may be read and you may receive a response from Anne Mitchell, Senior Admin Officer in the SEPA Orkney Office.

Consider the environment. Please don't print this e-mail unless you really need to.

From: Storm, Debbie
Sent: 07 March 2016 13:11
To: Sinclair, Douglas; Baird, Stuart
Cc: MacNaught, Kevin
Subject: RE: PAMP Report

FR7

Then we'll just make it up and say this is what we're going with.

From: Sinclair, Douglas
Sent: 07 March 2016 13:09
To: Storm, Debbie; Baird, Stuart
Cc: MacNaught, Kevin
Subject: RE: PAMP Report

FR6

Yes Debbie, that might work, although if SARF decide to publish as a result of the consultation with Directors that closes on Friday, then publication will likely occur next week. This then leaves us in a bit of limbo because if we are asked what our response is then in a formal sense we won't have one until managers decide what to do on the 5th. Could leave a slightly embarrassing gap...! And a challenge for us to deal with.

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From: Storm, Debbie
Sent: 07 March 2016 13:03
To: Sinclair, Douglas; Baird, Stuart
Cc: MacNaught, Kevin
Subject: RE: PAMP Report

FR5

Hi Douglas,

Thanks for contacting me on your day off! What are you going, man!!?

Stuart, very kindly, called this morning with a quick update but said you may know more, so thanks, this is great.

Immediate pressure off but we can maybe have a chat (the 4 of us) when we have more info after 5 April.

Cheers,
Debs

From: Sinclair, Douglas
Sent: 07 March 2016 12:03
To: Storm, Debbie; Baird, Stuart
Cc: MacNaught, Kevin
Subject: RE: PAMP Report

FR 4

Hi Debbie

Don't work Mondays – but hey, here I am – what are you doing man!

Anyway.....

Things look like they are to be delayed....or perhaps put completely in longer term abeyance. The SARF Directors have been asked to "approve" publication of the report and have been given until the end of this week to give their views. The way that the e-mail seeking their approval has been couched I would not be surprised if a decision not to publish was the conclusion. This would not be helpful albeit it would reduce short term stress. As we know about it's findings, I think we would still have to take action about Slice but would not have the published paper to help support that action – all very messy!

The paper seeking AMT approval for our proposed course of action has been with AMT for a few weeks and they have now sought to have it on the AMT agenda on the 5th April so I guess that certainty over what we will do about Slice/PAMP will have to await that meeting.....

Other than that, nothing much has changed.

I'll be back in the office on Tuesday, in Dingwall tomorrow.

All the best

D

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Consider the environment. Please don't print this e-mail unless you really need to.

FR3

From: Storm, Debbie
Sent: 07 March 2016 08:47
To: Sinclair, Douglas; Baird, Stuart
Cc: MacNaught, Kevin
Subject: PAMP Report

Morning!
Douglas I can never remember if it's Friday or Monday that you're not in so forgive me!

We're aware that the PAMP report is due to be published this week so just looking for an update as to any decision AMT might have made regarding the recommendations. We're keen to start getting lines together so if there's any update, can you drop use a line?

Cheers
Debs

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Mackinnon, Alison

FR 11

From: Sinclair, Douglas
Sent: 19 April 2016 11:45
To: Wells, Mark; Baird, Stuart; MacNaught, Kevin
Subject: RE: PRIVATE: aquaculture issues

Sensitivity: Private

Hi Mark

Happy to get together and I think you have identified a good number of the topical issues below.

We are probably the right folk at this stage.

All the best

D

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During absences from the office, my e-mails may be read and you may receive a response from Anne Mitchell, Senior Admin Officer in the SEPA Orkney Office.

FR 10

From: Wells, Mark
Sent: 18 April 2016 16:40
To: Sinclair, Douglas; Baird, Stuart; MacNaught, Kevin
Subject: PRIVATE: aquaculture issues
Importance: High
Sensitivity: Private

I have been discussing with Kevin our response to the PAMP report, but am conscious that there are a number of issues brewing in relation to the aquaculture sector and think it would be good if we could get together to discuss their implications individually but, more importantly, how we might manage the communications around them collectively.

As far as I'm aware, we have potential issues around:

1. The PAMP report

2. The phasing out of SLICE
3. Petition to Parliament on sea lice
4. Compliance statistics for fish farms in 2015-16
5. The change in charging regime for fish farms
6. The recent economic decline of the sector

There may be more? The timing is such that this may come to a head in mid-May, so it would be good if we could get together sooner rather than later? Is there anyone else we'd need to include in the discussion at this stage?

I'll see if I can set up a suitable time for us to talk.

Cheers

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Mackinnon, Alison

FR13

From: Ridgway, Ian
Sent: 03 May 2016 11:10
To: Wells, Mark
Cc: Best, Jennifer
Subject: RE: Pamp report

Hi Mark,

I think Jennifer Best is the person you need to speak to on the Science side of things. If there are aspects that don't fall within her ken she can suggest other assistance as required. Jen is based in Stirling so should be easy enough for you to catch up with her there. Please note that she does not work from the office on Friday's.

Jen - hope this is OK and you can fit Mark in at some point over next few days. If not can you put him in touch with someone else who can assist.

Regards

Ian

-----Original Message-----
From: Wells, Mark
Sent: 03 May 2016 10:58
To: Ridgway, Ian
Subject: Pamp report

FR13

Ian
I'm meeting Ops colleagues on Friday to discuss implications of Pamp report on sea louse chemicals - I'd like to speak to someone from science in advance if possible and wonder if you can advise on who that should be?

Cheers

Mark

Sent with Good (www.good.com)

Mackinnon, Alison

FR14

From: MacNaught, Kevin
Sent: 05 May 2016 15:11
To: Wells, Mark
Subject: SLICE
Attachments: SLICE QA for PAMP report.160205.DS.Draft.docx; Fish farm medicine - SEPA - DRAFT - 09.02.16.doc

Sensitivity: Confidential

Hi, these are the latest versions of the SLICE press release and Q&A.

Cheers

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FRIS

NEWS

from the
SCOTTISH ENVIRONMENT PROTECTION AGENCY

Xx 2016

SEPA to withdraw use of SLICE sea lice treatment

The Scottish Environment Protection Agency (SEPA) has decided, based on the latest evidence, that fish farm operators will not be authorised to use the sea lice medicine SLICE as of 31 March 2018.

This decision follows research commissioned by Scottish Aquaculture Research Forum (SARF), and undertaken by the Scottish Association for Marine Science (SAMS), to assess the impact of SLICE (emamectin benzoate) on the marine environment.

The SARF report shows subtle but detectable, and unexpected, impacts on the environment arising from the use of the medicine.

Douglas Sinclair, SEPA's fish farm specialist, said:

"SLICE is designed to kill sea lice and, in order to minimise the risk to other marine life and the environment, SEPA permitted its use only in accordance with licenses issued under the Water Environment (Controlled Activities) (Scotland) Regulations 2011.

"These licenses include conditions restricting the use of SLICE with the aim of limiting the risks to the environment and other marine life.

"Given concerns about changes in the way the medicine was being used SEPA proposed that SARF commission this study to better understand the possible effects of SLICE upon the environment. SEPA is an evidence-based organisation and as a regulator it is important that we continually monitor the environment and take effective action based on this.

"While previous studies have shown that SLICE has not had a significant impact on the marine environment and the impacts reported in this research are subtle, we have decided, based on the conclusions of SARF's report, that fish farms will not be permitted to use this medicine from 31 March 2018."

Fish farms will be able to continue to use SLICE subject to tight restrictions until the current (two-year) salmon growth cycle concludes. SEPA is in contact with the Veterinary Medicines Directorate (VMD) to provide recommendations to vets treating fish using Slice to minimise the potential for harm arising from its use, pending the removal of SLICE from the marketplace.

Commented [SD1]: This will depend on how happy our friends down in Surrey are to co-operate....this will become clear anon.

Ends

Media enquiries:

- Telephone: 01786 45 25 65
- Out of hours emergency media contact: 01698 839028

Distribution:

- If you want to receive all of SEPA's news releases, please email publicrelations@sepa.org.uk. You can also use this address if you want to be removed from our list.

FR16

SLICE – Q&A

PROTECT – these have been prepared by SEPA. The questions were posed for our research purposes and also to assist with drafting responses to any media enquiries and should not be disseminated/used by any other organisation.

- What impact is SLICE having on the environment and on species?
  SEPA expects that where fish farms are operated and substances such as Slice are used that the environment will be affected. The licensing system we have for farms is however designed to limit these effects to the area around and close to the fish farm cages. This study of the data on communities of animals living in the seabed shows a subtle but detectable and unexpected impact on communities of crustaceans in the seabed in waterbodies where there is a history of Slice use. The effect extends beyond the immediate vicinity of the fish farm. This means at sites where there is a history of Slice use there are fewer different species and fewer actual individual crustaceans compared to sites where it hasn't been used.

- What species have been impacted by these findings? And by what number have their abundance reduced?
  The measured effect is limited to crustaceans mainly small species of animals such as tiny shrimps which live in the seabed sand and mud. The changes in abundance are highly variable depending on where the samples are taken in relation to fish farms and on how often the treatment has been used. On average, sites where Slice treatments have been regularly used over several years will have 81% fewer crustaceans present than sites where the treatment has not been used.

- When (and how) did SEPA become aware of this?
  The Post-Authorisation Monitoring Project containing the evidence was published on XX Feb 2016. This was the outcome of a 2 year project which was given by the Scottish Aquaculture Research Forum (SARF) to the Scottish Association for Marine Science (SAMS) to undertake. The project was proposed by SEPA as the Agency is a Director of SARF. SEPA suggested to SARF that the project was worthwhile because:
  a) It was some time since research of this type had been done;
  b) The pattern of use of the product had changed since it was introduced;
  c) There was some discussion, for example with shellfishermen suggesting that unexpected effects were being observed.

- Why didn't SEPA spot this as the Scottish Association for Marine Science did the Post-Authorisation Monitoring Project study using SEPA's data?
  Our assessment of the condition of the seabed doesn't concentrate just on crustaceans but on the chemistry of the seabed and the overall health of the different groups of animals present there. It's a general view of the overall health of the seabed close to fish farms. Normally then, our routine monitoring would not necessarily spot a reduction in the numbers of crustaceans at any individual site and even if this were detected on a site-by-site basis it would not in itself necessarily be indicative of a problem. SEPA collects data on the condition of the seabed around fish farms and holds a great deal of this data. It is the scale of the data held by SEPA that means it is hard to analyse but also gives the information great value. But given the scale of work need to draw meaningful conclusions its not something that we routinely do and why a 2 year project was required to find this link.

- How long does SEPA expect that these impacts have been happening (before SEPA realised)?
  It is difficult to be certain. When Slice was first introduced in 1999-2000, a 5 year project to assess any impacts was established - the original Post Authorisation Assessment Project [link], its final report was published in 2005. This was a substantial piece of research funded by SEPA and a range of other partners which concluded that there was no discernible impact on the environment from the use of Slice and another sea louse medicine. It seems unlikely that this effect was present at that time as the study would have detected it. Since then, the patterns of use of Slice have changed which may has resulted in the observed effect arising. It's not therefore possible to be certain when such impacts first arose but probably sometime within the last 10 years.

- If fish farmers have been using SLICE at levels permitted by SEPA then how can this have happened?
  The amount of Slice that can be used for a treatment at any fish farm is limited by a series of equations. The aim of these equations is to restrict the amount of the medicine that can be used depending on how much might be around in the environment from previous treatments to avoid a build-up of residues and ensure any Slice remaining is at safe levels and that the residues do not last too long. While there is no suggestion that in most cases the safe levels of residues have been exceeded it is possible that changing use has seen an increase in the length of time that residues are present in the seabed. The extended duration of residues being present may have caused the unexpected effect that has been seen.

- What levels of SLICE would be regarded as safe/ normal in the environment? And what levels of SLICE have actually been found in the environment?
  SEPA sets a limit of 0.763 microgrammes of Slice per kilogram of wet sediment (0.763µg/kg) as a safe environmental standard which should ensure the protection of the environment beyond the vicinity of the fish farm. Data is collected on residue levels in the seabed around fish farms but these samples do not necessarily co-incide with the samples used to work out how many crustaceans are present in the seabed. In any typical year, a small number of farms are shown to have residues present at levels above this safe environmental standard. At this point it is clear that the safe environmental standard has not been breached in a widespread way across waterbodies but that the subtle effects on crustaceans is being seen at concentrations below the safe environmental standard.

- What action is SEPA taking to rectify this situation?
  SEPA takes this matter very seriously. We are an evidence based regulator and where there is robust evidence that some part of our regulatory regime is not providing environmental protection we will take steps to reduce or remove the potential for impacts. In this case having developed concerns about the use of Slice, SEPA sought that research be undertaken to assess whether there were subtle impacts. This report is the outcome of that research and SEPA intends to take the following steps to rectify the situation:
  a) *Restrict the use of the medicine to limit the potential for repetitive use and overuse of the product on fish that are currently stocked.*
  b) *Cease the use and discharge of the product at the end of the current growth cycle, in Spring 2018.*

- Is there a definitive date when fish farms will no longer be able to legally use SLICE?
  31 March 2018

- Could fish farms not just import SLICE and use it anyway?
  The importation of medicines is not something that SEPA regulates but were Slice to be used and released from a fish farm when it is no longer authorised by SEPA such use would be illegal.

- What action will SEPA take against fish farms which continue to use SLICE?
  The use and discharge of substances that are not authorised by conditions in CAR licences is illegal. Deliberate unauthorised releases of substances posing a significant environmental threat would normally be a matter dealt with under SEPA's Enforcement Policy.

- Are there viable and accessible alternatives which the fish farm industry can use instead of SLICE?
  There are other products available for the treatment of sea lice. What are they?

- Only a few months ago the fish farm industry was instructed not to use teflubenzuron. Now you are instructing fish farms not to use SLICE when you had previously stated it was safe to use. Do these findings undermine SEPA's reputation as an effective regulator of fish farms?
  Effective environmental regulation is about using scientific evidence to assess the impacts of development and activities on the environment and using the regulatory framework to allow development and use of the environment where possible but ensure that the impacts of such are within acceptable boundaries. The licensing of fish farms, including licensing the release of sea louse medicines is based around series of complex scientific assessments. At the time that these assessments were developed on the best available science and subject to independent review, they suggested that adequate environmental protection would be provided. Subsequent assessment of the impacts of the use of Calicide and Slice upon the environment has indicated higher than anticipated levels of residues (in the former case) and subtle unexpected impacts in the case of Slice.

- How many fish farms have used SLICE (e.g. in the last 2 years)? Where are these fish farms located?
  The product was used in 87 sites in 2014 and c70 sites in 2015 – although the numbers for 2015 are not yet complete. [We'll need to check these] The farms are located in a wide variety of locations on the West coast, the Western Isles and Shetland.

- I'm confused because the Compliance Assessment Scheme results for 2014 have just been published and it appears that many fish farms have performed very well. Given the findings regarding SLICE – why is this?
  The assessments undertaken in CAS are a site specific view of the performance of individual sites. This study is a widespread statistical assessment of the subtle effects of Slice on the environment rather than a measure of the way each site performs. The Compliance Assessment Scheme would not normally pick up the subtle effects reported in the PAMP study.

- Is SEPA certain that any fish farm medicines are safe to use? Why should we believe that SEPA won't backtrack on its view on other fish farm medicines in the future?
  SEPA will continue to review its position on all elements of fish farm regulation and if required will improve the means by which the regulation of fish farms is undertaken. We have no reason to believe that out position on other fish farm medicines will change in the near future.

- Should there be a moratorium on the use of all fish farm medicines until you can be confident that they are not having unexpected impacts?
  No, but if evidence demonstrates that a particular product is not safe then SEPA will take action to reduce or cease emissions of that product from fish farms.

- We got tipped off on these developments by the industry. Why has SEPA not proactively kept the public informed of these developments? Is SEPA in cahoots with SLICE manufacturers/ marketers?
  No, SEPA is not in cahoots with manufacturers of medicines or those who market such products.

Stuart's point to be added in - do you think we can take the opportunity to state that we expect the Industry to show their ability to innovate in the period until the withdrawal becomes effective?

Mackinnon, Alison

FR19

From: MacNaught, Kevin
Sent: 12 May 2016 08:44
To: Wells, Mark
Subject: FW: Aquaculture article
Attachments: SEPA to withdraw use of SLICE sea lice treatment - SEPAView article - DRAFT.docx

Sensitivity: Confidential

Hi Mark, do you want me to send this on to Douglas/ Stuart for input?
Cheers

Sent with Good (www.good.com)

FR17

-----Original Message-----
From: MacNaught, Kevin
Sent: Tuesday, May 10, 2016 02:55 PM GMT Standard Time
To: Wells, Mark
Subject: Aquaculture article

Hi Mark, to get the ball rolling I've drafted the attached article for SEPAView.

I haven't sent this on to Douglas or Stuart.

See what you think.

Cheers,

Kev

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FN18

SEPA to withdraw use of SLICE sea lice treatment

SEPA has informed fish farm operators that, based on the latest evidence, they will not be authorised to use the fish farm medicine SLICE as of 31 March 2018. Here we look at how we have come to this decision to help protect the environment, and how we feel this decision will benefit the aquaculture industry in the long run.

Aquaculture is one of the most important contributors to Scotland's economy, helping to underpin sustainable economic growth.

It is understood that aquaculture can have an adverse effect on the environment and, in order to negate this, SEPA promotes compliance with legislation and sustainability through the Water Environment (Controlled Activities) (Scotland) Regulations 2011.

Effective environmental regulation is about using scientific evidence to assess the impacts of developments and activities on the environment, and using the regulatory framework to ensure that any environmental impacts are within acceptable boundaries.

We are an evidence based regulator and we undertake monitoring to ensure that the businesses we regulate are not having a negative impact on the environment.

Where there is robust evidence to suggest that some part of our regulatory regime is not providing environmental protection we will take action to reduce or remove the potential for impacts.

SEPA carries out general assessments to understand the overall health of the seabed, close to fish farms. Through the analysis of this data we have become concerned that there may be a subtle but detectable, and unexpected, impact on the environment arising from the use of SLICE (emamectin benzoate).

SLICE is designed to kill sea lice and, the licencing system includes conditions restricting the use of SLICE with the aim of limiting any potential risks to the environment and other marine life.

To ensure the environment is protected we have undertaken studies into the health of the seabed near to fish farms at Seil Sound and Loch Shell. However, these studies have confirmed our concerns by demonstrating the subtle but detectable impacts on the environment arising from the use of SLICE.

This means that at sites where there is a history of SLICE use there are likely to be fewer different species and fewer individual crustaceans compared to sites where it hasn't been used.

While previous studies have shown that SLICE has not had a significant impact on the marine environment, and the impacts reported in this research are subtle, we have decided that fish farm operators will not be authorised to use SLICE as of 31 March 2018.

This is not a decision we have taken lightly. We believe that, on the basis of the available evidence, this is the right decision for the environment, and in the long run it will help the aquaculture industry also.

We take this matter very seriously, but it is important to keep it in perspective. SEPA permitted the use of SLICE only in accordance with licences issued under the Water

Environment (Controlled Activities) (Scotland) Regulations 2011, and set a limit as a safe environmental standard which should ensure the protection of the environment beyond the vicinity of the fish farm.

The evidence shows that a small number of fish farms appear to have residues of SLICE present at levels at the borderline of this safe environmental standard.

However, at this point, it is clear that the safe environmental standard has not been breached in a widespread way across water bodies.

We have been working closely with the Scottish Government and with our relevant key partner organisations (Xxx) regarding this decision, and we will continue to work closely with them on this issue.

Commented [MK1]: Which organisations want to be a part of this?

We will also continue to work closely with the aquaculture industry. Fish farms will be able to continue to continue to use SLICE, subject to tight restrictions, until the current (two-year) salmon growth cycle concludes.

Innovation in producing alternative treatments to SLICE will be required by the industry before the withdrawal comes into effect, and this is something we are confident the industry is well placed to achieve.

We want businesses to play their part in helping Scotland to successfully realise the opportunities in creating social and economic success through the innovation needed to live within planetary constraints.

It is healthy and important for businesses to innovate and the Scottish Aquaculture Innovation Centre was established in 2013 to help the aquaculture sector to do this by producing innovative collaborations with the research community.

This is an exciting time for SEPA and for Scotland. The Regulatory Reform (Scotland) Act 2014 has provided SEPA with one of the greatest opportunities since its formation. We will in the near future have additional enforcement powers including the ability to issue fixed and variable monetary penalties to help change behaviours in non-compliant businesses.

The launch of our new survey vessel in May will specifically monitor the seabed around fish farms and will help us to gain even more insightful environmental data which we can use to hold businesses to account as necessary.

These developments will help SEPA to target its effort in getting all businesses to comply with environmental regulations, drive as many regulated businesses as possible to move beyond compliance, and demonstrate how environmental success can also mean economic success.

Ends

Mackinnon, Alison

FR 27

From: MacNaught, Kevin
Sent: 27 May 2016 11:21
To: Sinclair, Douglas; Baird, Stuart
Cc: Wells, Mark
Subject: RE: Aquaculture
Attachments: SLICE story - latest DRAFT.docx

Sensitivity: Confidential

Hi, I've pulled together a table of partner organisations I think we'd need to inform about the SLICE SEPAView article in advance (but let me know if I've missed anyone out) – so that we'd be in a position to upload the article as soon as the PAMP report is live.

Good to firm up who would be sharing with them and when (even roughly) if you can add in below?

Partner	Who from SEPA sharing article with partner	When sharing
Scottish Association for Marine Science		
Scottish Aquaculture Research Forum		
Marine Scotland		
Scottish Government - Greener Desk	Kevin	
Scottish Government - Sponsor	Mark	
Scottish Aquaculture Innovation Centre		

We've got the following photos to help illustrate the article on SEPAView – but let me know if you have any photos you would rather are used.

Regards,

Kevin

From: MacNaught, Kevin
Sent: 19 May 2016 18:16
To: Sinclair, Douglas; Wells, Mark; Baird, Stuart
Subject: RE: Aquaculture
Sensitivity: Confidential

FR26

Thanks Douglas, aware that other organisations will have interest in this and it may impact on them.

I think the next step with this is to firm up:

- Who we are going to share this with in advance
- Who from SEPA will share it with them
- And when we're going to share it with them.

This might highlight sections which need to be altered (e.g. NewDEPOMOD).

And then hopefully we'd be in a position to upload this to SEPAView as soon as the PAMP report goes live.

Cheers,

Kevin

From: Sinclair, Douglas
Sent: 18 May 2016 16:47
To: Wells, Mark; MacNaught, Kevin; Baird, Stuart
Subject: RE: Aquaculture
Sensitivity: Confidential

FR25

Hi folks

I have made a few small further tweaks to address Kevin's points below:

In para 6 - I wonder if we can clarify what we mean by 'confirmed a more extensive spread within the marine environment.' It's just that in the previous para we say 'there is little evidence of widespread breaches of the standard...'
There's a difference in meaning here, the Shuna Sound work found that residues were distributed more widely than anticipated but these residues were present at concentrations below the safe environmental standard. So, in essence it was found in more places than we might have expected in Shuna Sound albeit at relatively low concentrations.

Para 7 - we're wanting to go ahead with this ASAP so thinking this para would need to be cut if the SARF research isn't to be published any time soon?

I think we are wanting to do this as soon as we can but I think it might be best to be timed to coincide with the publication of the SARF work – also, Alison York has been having a look at the legal aspects of the withdrawal of the product and Stuart and I are seeking to bottom out some issues with her. It might be best if we awaited that conversation although Stuart might take a different view?

Para 12 - would SAMS be annoyed if we release details of NewDEPOMOD before they've announced it as think they're planning a press release about it? Also think there are some issues with New DEPOMOD which need ironed out? Maybe they'd like us to mention it in this article though?
SAMS are champing at the bit to get a press release out on the new model, we are still confirming its effectiveness and are perhaps coming to the view that we won't look for it to be used in anger until later in the year. That might be no reason for us not to mention it in the story but we'd need to make sure that SAMS and Marine Scotland (who paid for the development work) are happy for us to do so. It might be that they will want to issue their own press release(s) on that issue and we'd just want the chance to make sure that their press release is clear about when we will accept applications using it

Mark, I take your point regarding withdrawal vs the possibility of further evidence changing that decision. There are reasons for my change to the text to alter the emphasis. I think we would always be open to new or refined evidence or research influencing decisions and in the two year phase out period we couldn't close the door to that possibility, especially when the SAMS PAMP research report and our own data analysis is not claiming an absolute cause and effect relationship. I think the chance of research being undertaken which undermines the decision to phase out Slice use is fairly remote but it is always possible. The AMT paper does also leave that particular door ajar in para 6.6 of the AMT paper (see excerpt below) we say: *".....Only if SEPA receives sufficient evidence that the treatment regime could be amended in a way that offered efficacious treatments to farmed salmon and protected the environment from subtle but damaging impacts would ASMG advise the re-introduction of Slice to CAR licences."*

> 6.6 SEPA officers therefore met representatives of the manufacturers, – MSD Animal Health, to discuss recent findings, explain SEPA's concerns. MSD representatives noted SEPA's concerns, but reserved their position, expressing a keenness to maintain a dialogue with SEPA while they consider their options and discuss the issue with the industry and the VMD. Only if SEPA receives sufficient evidence that the treatment regime could be amended in a way that offered efficacious treatments to farmed salmon and protected the environment from subtle but damaging impacts, would ASMG advise the re-introduction of Slice to CAR licences.

As I say, I think the chances are pretty remote but I understand that the manufacturers are proposing to commission further research and it would be hard for us to refuse to consider new results if we were content that the work was properly founded and effectively executed.

I didn't speak to Scott Landsburgh on this issue on Friday the 6th. I think we should do so but much closer to the point where we will publish. My fear of engaging too far ahead of time is that they may say that they do not wish to be part of our story but use the early sight of our text to launch a press story of their own losing us the initiative we crave. SARF did not specify a date for publication of the PAMP report it awaits a revision to the report to add a preface. I think that will happen shortly and I should be given sight of this final report a day or two before it goes live on the SARF website. I think at that point we could easily approach SSPO – John Webster, the SSPO Technical Director is also a SARF Director and will see the SARF/PAMP report on the same day as me and ask for their comments.

If we are going ahead before the SARF/PAMP report is published then I think as Kevin points out that we need to remove references to it in our story.

Whenever we publish, Stuart and I will need to have letters to go to the sector and MSD – who own Slice, at the same time that we publish the story, telling them directly of our chosen course of action.

Does this help?

D

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I no longer work on Mondays, normally available Tuesday - Friday.
During absences from the office, my e-mails may be read and you may receive a response from Anne Mitchell, Senior Admin Officer in the SEPA Orkney Office.

From: Wells, Mark
Sent: 18 May 2016 13:59
To: MacNaught, Kevin; Sinclair, Douglas; Baird, Stuart
Subject: RE: Aquaculture
Sensitivity: Confidential

FR24

Thanks all for the clarifications. I only have one query - the paper to AMT asked for, and got, a decision to phase out Slice, while in the article we say we will unless we see compelling evidence to the contrary. I don't think that position was put to AMT? If we say in the article we might not phase it out, but have a previous decision that we will, it could cause difficulties if the AMT paper and minute was FOI. Could we please clarify that one, and we may need to revisit the AMT decision.

Two things remain - do we know when the report will be published, and do we know whether anyone else is willing to join us in telling this story?

Cheers

Mark

Sent with Good (www.good.com)

FR23

-----Original Message-----
From: MacNaught, Kevin
Sent: Tuesday, May 17, 2016 07:17 PM GMT Standard Time
To: Sinclair, Douglas; Baird, Stuart
Cc: Wells, Mark
Subject: RE: Aquaculture

Thanks, just had a couple of points.

In para 6 - I wonder if we can clarify what we mean by 'confirmed a more extensive spread within the marine environment.' It's just that in the previous para we say 'there is little evidence of widespread breaches of the standard...'

Para 7 - we're wanting to go ahead with this ASAP so thinking this para would need to be cut if the SARF research isn't to be published any time soon?

Para 12 - would SAMS be annoyed if we release details of NewDEPOMOD before they've announced it as think they're planning a press release about it? Also think there are some issues with New DEPOMOD which need ironed out? Maybe they'd like us to mention it in this article though?

Let me know your thoughts.

In terms of next steps - think the next step is that partner organisations are made aware of our plans?

Cheers,
Kevin

Sent with Good (www.good.com)

-----Original Message-----
From: Sinclair, Douglas
Sent: Tuesday, May 17, 2016 02:23 PM GMT Standard Time
To: MacNaught, Kevin; Baird, Stuart
Cc: Wells, Mark
Subject: RE: Aquaculture

FR22

Hi folks

I have added further edits on top of Stuart's. You'll see I have changed the emphasis somewhat from *we are withdrawing permission to use Slice but allowing some use meantime,* to *we are restricting use for the next two years to reduce risk and allow clearer science to be undertaken into cause and effect, and unless a compelling case is made it will be withdrawn.*

This is because I understand that MSD who own Slice intend to pay for further research in an attempt to demonstrate that the product is in fact safe. We are also continuing our own monitoring work during this summer. Were MSD able to show that the risk is actually much lower than the PAMP study suggests and we have not found issues to concern us in our own monitoring then we might reconsider our position during the 2y interregnum. I think however this is highly unlikely.

Happy to discuss as required.....

D

Douglas Sinclair
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I no longer work on Mondays, normally available Tuesday - Friday.
During absences from the office, my e-mails may be read and you may receive a response from Anne Mitchell, Senior Admin Officer in the SEPA Orkney Office.

Consider the environment. Please don't print this e-mail unless you really need to.

From: MacNaught, Kevin
Sent: 16 May 2016 14:55
To: Sinclair, Douglas; Baird, Stuart
Cc: Wells, Mark
Subject: RE: Aquaculture
Sensitivity: Confidential

Hi Douglas/ Stuart, is there any word on how the SARF board meeting went and if there was any indication on plans for publishing the report etc?

Cheers,

Kevin

From: MacNaught, Kevin
Sent: 13 May 2016 11:53
To: Sinclair, Douglas; Baird, Stuart
Cc: Wells, Mark
Subject: Aquaculture
Sensitivity: Confidential

Hi Douglas/ Stuart, Mark and I have been considering the proposed article for SEPAView. Please see the draft article attached for your amends/ approval.

Regards,

Kevin

Kevin Macnaught
Communications Officer
Scottish Environment Protection Agency | Strathallan House | Castle Business Park | Stirling FK9 4TZ

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FR28

Evidence and innovation hold the key to sustainable fish-farming

Aquaculture is an important and ambitious industry in Scotland, helping underpin a successful and sustainable rural economy particularly in the Highlands and Islands. Ensuring that this vital sector operates within the capacity of our world-class coastal environment is essential and a key role for SEPA. One issue in particular, the control of sea lice, continues to prove particularly challenging, but also presents an opportunity to position Scotland at the forefront of innovation and development in marine fish-farming.

Scotland's fish-farming sector is important to a vibrant and sustainable rural economy. Ensuring it can continue to thrive, while protecting our world class coastal environment, is a vital consideration both for the industry and for SEPA as Scotland's principal environmental regulator. New evidence regarding the potential environmental impacts of treatments for sea lice has prompted SEPA and the industry to take swift action, and tap into the sector's capacity for innovation, research and development, to secure a sustainable future for Scotland's aquaculture.

Sea lice are small marine parasites which occur naturally on many species of fish, but can be a problem when large numbers of fish are concentrated in fish-farms. There are a number of methods of controlling sea lice, including the use of authorised medicines either as a bath or in-feed treatment.

The use of these treatments and the resulting release to the marine environment is regulated by SEPA, and is carefully controlled by conditions included in our fish farm licences informed by detailed modelling of the possible impacts from their use. Those conditions are set using the best available evidence, and based on the anticipated frequency and dose of treatment, to ensure the residues in the environment are within independently derived safe environmental standards and environmental impacts are within acceptable levels.

SEPA and the fish-farming sector carry out general monitoring of the overall health of the seabed close to fish farms. This shows that at a small number of fish farms residues from the use of SLICE are found to present at levels around or slightly above the environmental quality standard, although at this point there is little evidence of widespread breaches of this safe environmental standard across sea lochs or voes.

While previous monitoring of fauna has generally not shown significant impacts on marine animals in the wider marine environment, we have become aware of anecdotal claims that sea louse treatments might be having an unexpected adverse environmental impact at this scale, resulting in less biodiversity and reductions in some crustacean populations. In response, we have undertaken a more detailed and extensive study into the health of the seabed near to fish farms at Shuna Sound. This study has confirmed a more extensive spread within the marine environment of low levels of the residues arising from the use of the sea louse treatment SLICE, whose active ingredient is emamectin benzoate, than had been expected when the medicine was first authorised or had been predicted by detailed modelling.

Since our regulatory process is based on the best available scientific evidence, we invited the Scottish Aquaculture Research Forum (SARF) to commission research to further analyse our data to determine whether there is compelling evidence of the environmental impacts suggested by the anecdotal claims. This analysis identified a subtle but detectable, and unexpected, association between impact on the marine environment and the use of SLICE.

The data is highly complex and the conclusions are not absolute but an association is clearly indicated.

We are also aware and are concerned that the frequency and dose of SLICE treatments have regularly exceeded what was expected when the current licence framework was developed. There is no suggestion that the treatments are breaching the licences set by SEPA but the new treatment patterns may reflect the fact that the treatment is becoming less effective probably as sea lice become more resistant to the medicine.

Where robust evidence suggests that some part of our regulatory regime is not providing the expected and required level of environmental protection, we have a duty to take action to reduce or remove the potential for those impacts. In this case, and following careful consideration, we have decided to change the way in which SLICE use is permitted by conditions in fish farm licences. This will allow continued use of the medicine but subject to tighter restrictions on use. These arrangements will remain in place for a period of two years allowing the sector or the company which markets SLICE to carry out further research to confirm or confound the apparent link between SLICE use and unexpected environmental effects. SEPA will also be undertaking further analysis and monitoring work during this period. If during the next two years no compelling case is made to support the continued use of the product, authorisations for the use of SLICE will be withdrawn by SEPA.

The implementation of the Regulatory Reform (Scotland) Act two years ago also provides SEPA with an opportunity to review the regulatory framework under which fish-farms operate to ensure it continues to provide adequate protection of our environment, while supporting a thriving and sustainable industry. The Act also provides SEPA with new enforcement powers through which we aim to encourage compliance with the conditions set out in our licences.

We have informed fish farm operators of SEPA's decision that, unless we see new and compelling evidence to support continued use, our authorisation of SLICE will be phased out in 2018. We are also working in partnership with the Industry, the Scottish Government, the Scottish Aquaculture Innovation Centre and other key partners, to explore the potential for the development of alternative means of controlling sea lice, which minimise the risk to our marine environment. The challenge of controlling sea lice in fish farms is not unique to Scotland, and the research and development of these alternative means represents a significant opportunity for Scotland to establish itself as a leader in the field, and could benefit both the aquaculture sector and Scotland's wider economy in the long run.

A new computer model, created by researchers at the Scottish Association for Marine Science (SAMS), with support from the Scottish Government and SEPA, will become a key tool in the future regulation of fish farms. This model will be available for use in applying for fish farm licences later this year and will enable a better understanding of how discharges from fish farms affect the seabed. NewDEPOMOD will replace the current AutoDEPOMOD model, which has been in use since 1999. And this month SEPA will be officially launching a new survey vessel, the Brian Miller, designed specifically to enhance our capability to monitor the environmental impacts of marine fish farms.

SEPA's statutory purpose is to protect and improve the environment, where possible in ways which contribute to health and well-being and sustainable economic growth. Our approach to working with Scotland's aquaculture industry to help turn this environmental challenge into an opportunity to ensure a thriving and sustainable fish-farming sector is just one example of us putting this purpose into practice.

Ends

F29

Mackinnon, Alison

From: MacNaught, Kevin
Sent: 30 June 2016 13:41
To: Wells, Mark
Subject: Aquaculture - compliance

Sensitivity: Confidential

Hi Mark, I've got some questions I was thinking about putting forward to Douglas and Stuart to assist with drafting an article for SEPAView on the compliance results. The thinking was that this would be uploaded to SEPAView when the CAS results go live to pre-empt interest from the media.

Aware though that it's all a bit unclear as to what is happening with various different aquaculture issues at the moment and I don't want to make things more complicated by entering into the fray with this before these issues have been resolved.

I wanted to get your take on whether I should hold fire with this for now?

Cheers,
Kev

These are the questions I was going to put forward -

- What are the final compliance figures for the aquaculture sector? How does this compare to previous years?
- Why has there been an increase in non-compliance in the aquaculture sector?
- Is the increase in non-compliance related to/ caused by the issue with SLICE?
- How does SEPA regulate the aquaculture industry?
- What has SEPA been doing to ensure that aquaculture sector companies comply with their licence this year?
- How many site visits to fish farms have we undertaken this year compared to previous years?
- Do we rely purely on self-monitoring for fish farm sites? And is it acceptable for fish farms to continue to self-monitor at all given the compliance results?
- Is SEPA doing anything differently (in terms of regulation) which may explain why there has been an increase in non-compliance in the sector this year?
- What are the issues we are experiencing in bringing aquaculture sector companies to compliance?
- How do we plan to tackle non-compliance in the aquaculture sector in the future? Are we going to be doing anything differently given the compliance results this year?

Kevin Macnaught
Communications Officer
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Mackinnon, Alison

From: Baird, Stuart
Sent: 05 August 2016 09:11
To: MacNaught, Kevin
Cc: Wells, Mark; Sinclair, Douglas
Subject: RE: aquaculture
Attachments: SLICE story - 5 Aug 2016.docx

FK 31

Hi Kevin,

latest version. I have tried to get SAIC and SAMS but no luck as yet, I'll keep trying.

Stuart

FK 30

-----Original Message-----
From: MacNaught, Kevin
Sent: 05 August 2016 09:00
To: Baird, Stuart
Subject: Re: aquaculture

Hi Stuart, do you think you'll be able to send Mark and I the updated sepaview article this morning?
Cheers,
Kev

Sent with Good (www.good.com)

FPE39

Evidence and innovation hold the key to sustainable fish-farming

Aquaculture is an important and ambitious industry in Scotland, helping underpin a successful and sustainable rural economy particularly in the Highlands and Islands. Ensuring that this vital sector operates within the capacity of our world-class coastal environment is essential and a key role for SEPA. One issue in particular, the control of sea lice, continues to prove particularly challenging, but also presents an opportunity to position Scotland at the forefront of innovation and development in marine fish-farming.

Scotland's fish-farming sector is important to a vibrant and sustainable rural economy. Ensuring it can continue to thrive, while protecting our world class coastal environment, is a vital consideration both for the industry and for SEPA as Scotland's principal environmental regulator. New evidence regarding the potential environmental impacts of treatments for sea lice has prompted SEPA and the industry to take swift action, and tap into the sector's capacity for innovation, research and development, to secure a sustainable future for Scotland's aquaculture.

Sea lice are small marine parasites which occur naturally on many species of fish, but can be a problem when large numbers of fish are concentrated in fish-farms. There are a number of methods of controlling sea lice, including the use of authorised medicines either as a bath or in-feed treatment such as Emamectin Benzoate.

The use of these treatments and the resulting release to the marine environment is regulated by SEPA, and is carefully controlled by conditions included in our fish farm licences informed by detailed modelling of the possible impacts from their use. Those conditions are set using the best available evidence, and based on the anticipated frequency and dose of treatment, with the aim of ensuring that the residues in the environment are within independently derived safe environmental standards and environmental impacts are within acceptable levels.

SEPA and the fish-farming sector carry out general monitoring of the overall health of the seabed close to individual fish farms, which shows that at a small number of fish farms residues from the use of Emamectin Benzoate are found to present at levels around or slightly above the safe environmental standard, although at this point there is little evidence of widespread breaches of the safe environmental standard across sea lochs or voes.

While previous monitoring of seabed fauna has generally not shown significant impacts on marine animals in the wider marine environment, we have become aware of anecdotal claims that sea louse treatments might be having an unexpected adverse environmental impact at this scale, resulting in less biodiversity and reductions in some crustacean populations. In response, we have undertaken a more detailed and extensive study into the health of the seabed in the Shuna Sound, area, in which there are a number of fish farms which have used in-feed sea louse treatments. This study has confirmed a more extensive spread within the marine environment of low levels of the residues arising from the use of the sea louse treatment Slice, whose active ingredient is Emamectin Benzoate, than had been expected when the medicine was first authorised or had been predicted by detailed modelling.

Since our regulatory process is based on the best available scientific evidence, we invited the Scottish Aquaculture Research Forum (SARF) to commission research to further analyse our data to determine whether there is compelling evidence of the environmental impacts suggested by the anecdotal claims. This analysis identified a subtle but detectable, and unexpected, association between impact on the marine environment and the use of Slice. The data is highly complex and the conclusions are not absolute but an association is clearly indicated.

We are also aware and are concerned that in many cases the frequency and dose of Slice treatments have regularly exceeded what was expected when the current licence framework was developed. In most cases there is no suggestion that the treatments are breaching the licences set by SEPA but it is possible that the fate and behaviour of the medicine once it has been fed to fish differs from that which was assessed when setting the safe environmental standard. The new treatment patterns may reflect the fact that the treatment is becoming less effective, probably as sea lice become more resistant to the medicine.

Where robust evidence suggests that some part of our regulatory regime is not providing the expected and required level of environmental protection, we must take action to reduce or remove the potential for those impacts. In this case, and following careful consideration, we are intending to change the way in which Slice use is permitted by conditions in fish farm licences. This will allow continued use of the medicine but subject to tighter restrictions on use. These arrangements are likely to remain in place for a period of two years allowing the sector or the company which markets Slice to carry out further research to confirm or confound the apparent link between Slice use and unexpected distribution of residues and possible environmental effects. SEPA will also be undertaking further analysis and monitoring work during this period. If during the next two years no compelling case is made to support the continued use of the product, it is likely that the ability to use Slice will be phased out completely.

We have informed fish farm operators of SEPA's position that, unless we see new and compelling evidence to support continued use, the ability to use Slice is likely to be phased out in 2018. We are also working in partnership with the Industry, the Scottish Government, the Scottish Aquaculture Innovation Centre and other key partners, to explore the potential for the development of alternative means of controlling sea lice, which minimise the risk to our marine environment. The challenge of controlling sea lice in fish farms is not unique to Scotland, and the research and development of these alternative means represents a significant opportunity for Scotland to establish itself as a leader in the field, and could benefit both the aquaculture sector and Scotland's wider economy in the long run.

A new computer model, created by researchers at the Scottish Association for Marine Science (SAMS), with support from the Scottish Government and SEPA, will become a key tool in the future regulation of fish farms. This model will be available for use in applying for fish farm licences later this year and will enable a better understanding of how discharges from fish farms affect the seabed. NewDEPOMOD will replace the current AutoDEPOMOD model, which has been in use since 1999. SEPA recently launched a new survey vessel, the Brian Miller, designed specifically to enhance our capability to monitor the environmental impacts of marine fish farms.

SEPA's statutory purpose is to protect and improve the environment, where possible in ways which contribute to health and well-being and sustainable economic growth. Our approach to working with Scotland's aquaculture industry to help turn this environmental challenge into

an opportunity to ensure a thriving and sustainable fish-farming sector is just one example of us putting this purpose into practice.

Ends

Mackinnon, Alison

FR 35

From: MacNaught, Kevin
Sent: 05 August 2016 13:16
To: Baird, Stuart
Subject: RE: Draft SEPA view article

Hi Stuart, my suggested text below.
Cheers,
Kevin

'As discussed during the teleconference, please find a draft article attached, for your information, which aims to present a balanced view of some of the issues surrounding the control of sea-lice in light of the imminent publication of the SARF PAMP-2 report. We plan to publish the article on SEPA's online magazine 'SEPAView', shortly before the SARF report is published, on Wednesday 10 August.

We would very much like the article to be inclusive and would therefore like to offer SSPO the opportunity to provide a contribution to the article. If you would like to make a contribution to the article then can you please send this to me by the end of the day on Monday 8th August.

Once we have received all contributions we will re-circulate the article for a quick accuracy check before publishing.'

FR 34

From: Baird, Stuart
Sent: 05 August 2016 12:49
To: MacNaught, Kevin
Subject: Draft SEPA view article

Kevin, just getting prepared a bit and looking for some assistance.

I will send a separate e-mail to each of the parties who are interested in making a contribution, SAIC and SAMS so far have agreed to consider doing so but want to ensure that this is worded in a way that makes it clear that whilst we would welcome a contribution

'As discussed during the teleconference, we have prepared a draft article for publication on SEPA's online magazine 'SEPA View', this aims to present a balanced view of some of the issues surrounding the control of sea-lice in light of the imminent publication of the SARF PAMP-2 report.

We would very much like the article to be inclusive and would therefore offer the opportunity for SSPO to provide a contribution to the article. If you feel that you would like to make such a contribution then please would you provide this to me by the end of the day on Monday 8th August.

Once we have received all contributions we would intend to re-draft the article and then re-issue for a quick check before publishing, which we would aim to do shortly before the SARF report is published.'

Would you mind having a go at this wording as I'm not clear how we would normally take account of possible contributions etc.

Cheers

Stuart

Mackinnon, Alison

From: Baird, Stuart
Sent: 08 August 2016 10:32
To: MacNaught, Kevin
Subject: FW: Confidential - SEPA sea lice article for contributions

FR37

From: Robin Shields [mailto:robin@scottishaquaculture.com]
Sent: 08 August 2016 09:56
To: Baird, Stuart
Subject: RE: Confidential - SEPA sea lice article for contributions

Dear Stuart,

Just a quick note to relay that SAIC consensus is that the emamectin article stands well as currently drafted, many thanks for offering the option to contribute.

We look forward to seeing the published article and will be on standby in case publication of the PAMP report generates any media enquiries regarding innovative sea lice treatments, etc.

Kind regards,

Robin.

Dr Robin Shields
Aquaculture Innovation Manager
Scottish Aquaculture Innovation Centre
(t) 01786 278324 **(w)** scottishaquaculture.com Connect+Collaborate

Delivering industry success through research partnerships

Scottish Aquaculture Innovation Centre

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Innovation Centres
Supported by The Scottish Funding Council, Highlands and Islands Enterprise and Scottish Enterprise.

Proud to support the winning projects of the **Innovation Award** at the Scottish Food & Drink Excellence Awards 2016 and **Innovative Collaboration Award** at the Scottish Enterprise Life Science Awards 2016.

The Scottish Aquaculture Innovation Centre is hosted by the University of Stirling and based at Unit 19, Scion House, Stirling University Innovation Park, Stirling FK9 4NF.

FR36

From: Robin Shields
Sent: 08 August 2016 08:59
To: 'Baird, Stuart' <stuart.baird@sepa.org.uk>
Subject: RE: Confidential - SEPA sea lice article for contributions

Dear Stuart,

Thank you for the very interesting draft emamectin article. Did you have a format and location in mind for 3rd party inputs?

On first read-through, the article strikes me as a clearly written stand-alone piece, in which brief signposting by SEPA of sectoral innovation efforts (including those supported by SAIC) may be appropriate, rather than other parties contributing their own content.

Those are my initial thoughts, but I'll discuss in confidence with senior colleagues and we'll revert to you soonest.

Best regards,

Robin.

Dr Robin Shields
Aquaculture Innovation Manager
Scottish Aquaculture Innovation Centre
(t) 01786 278324 **(w)** scottishaquaculture.com Connect+Collaborate

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FR 33

From: Baird, Stuart [mailto:stuart.baird@sepa.org.uk]
Sent: 05 August 2016 17:31
To: Robin Shields <robin@scottishaquaculture.com>
Subject: Confidential - SEPA sea lice article for contributions

Robin,

as discussed, please find a draft article attached, for your information, which aims to present a balanced view of some of the issues surrounding the control of sea-lice in light of the imminent publication of the SARF PAMP-2 report. We plan to publish the article on SEPA's online magazine 'SEPAView', shortly before the SARF report is published, on Wednesday 10 August.

We would very much like the article to be inclusive and would therefore like to offer SAIC the opportunity to provide a contribution to the article. If you would like to make a contribution to the article then can you please send this to me by the end of the day on Monday 8th August.

Once we have received all contributions we will re-circulate the article for a quick accuracy check before publishing.

Regards

Stuart

Mackinnon, Alison

FOI 18

From: Wells, Mark
Sent: 09 August 2016 09:06
To: Ahearn, Terry
Cc: Green, Jo
Subject: SLICE story

Terry
I understand Calum is speaking with SSPO regarding comms around the SLICE report.

Notwithstanding the outcome of that meeting, I am copying you below the current draft of the story as developed by us – if we do go ahead tomorrow there isn't much time for review and sign-off, so I wanted you to have the latest version, which I have tweaked slightly in light of yesterday's launch:

Evidence and innovation hold the key to sustainable fish-farming

Aquaculture is an important and ambitious industry in Scotland, helping underpin a successful and sustainable rural economy particularly in the Highlands and Islands. Ensuring that this vital sector operates within the capacity of our world-class coastal environment to support it is essential and a key role for SEPA. One issue in particular, the control of sea lice, continues to prove particularly challenging. But it also presents an opportunity to position Scotland at the forefront of innovation and development which create lasting prosperity and viability for the industry.

Scotland's fish-farming sector is important to a vibrant and sustainable rural economy. Ensuring it can continue to thrive, while protecting our world class coastal environment, is a vital consideration both for the industry and for SEPA as Scotland's principal environmental regulator. New evidence regarding the potential environmental impacts of treatments for sea lice has prompted SEPA and the industry to take swift action, and tap into the sector's capacity for innovation, research and development, to secure a viable and prosperous future for Scotland's aquaculture.

Sea lice are small marine parasites which occur naturally on many species of fish, but can be a problem when large numbers of fish are concentrated in fish-farms. There are a number of methods of controlling sea lice, including the use of authorised medicines either as a bath, or an in-feed treatment such as Emamectin Benzoate.

The use of these treatments, and the resulting release to the marine environment, is regulated by SEPA, and is carefully controlled by conditions included in our fish farm licences informed by detailed modelling of the possible impacts from their use. Those conditions are set using the best available evidence, and based on the anticipated frequency and dose of treatment, with the aim of ensuring that the residues in the environment are within independently derived safe environmental standards and environmental impacts are within acceptable levels.

SEPA and the fish-farming sector carry out general monitoring of the overall health of the seabed close to individual fish farms. This monitoring shows that at a small number of fish farms residues from the use of Emamectin Benzoate are found to be present at levels around or slightly above the safe environmental standard, although at this point there is little evidence of widespread breaches of the safe environmental standard across sea lochs or voes.

While previous seabed monitoring has generally not shown significant impacts on marine animals in the wider marine environment, we have become aware of anecdotal claims that sea louse treatments might be having an unexpected adverse environmental impact at this scale, resulting in less biodiversity and reductions in some crustacean populations. In response, we have undertaken a more detailed and extensive study into the health of the seabed in the Shuna Sound area, in which there are a number of fish farms which have used in-feed sea louse treatments. This study has confirmed a more extensive spread within the marine environment of low levels of the residues arising from the use of the sea louse treatment

Slice, whose active ingredient is Emamectin Benzoate, than had been expected when the medicine was first authorised, or had been predicted by detailed modelling.

Since our regulatory process is based on the best available scientific evidence, we invited the Scottish Aquaculture Research Forum (SARF) to commission research to further analyse our data to determine whether there is compelling evidence of the environmental impacts suggested by the anecdotal claims. This analysis identified a subtle but detectable, and unexpected, association between impact on the marine environment and the use of Slice. The data are highly complex and the conclusions are not absolute, but an association is clearly indicated.

We are also aware, and are concerned, that in many cases the frequency and dose of Slice treatments have regularly exceeded what was expected when the current licence framework was developed. In most cases there is no suggestion that the treatments are breaching the licences set by SEPA, but it is possible that the fate and behaviour of the medicine once it has been fed to fish differ from those which were assessed when setting the safe environmental standard. The new treatment patterns may reflect the fact that the treatment is becoming less effective, probably as sea lice become more resistant to the medicine.

Where robust evidence suggests that some part of our regulatory regime is not providing the expected and required level of environmental protection, we must take action to reduce or remove the potential for those impacts. In this case, and following careful consideration, we are intending to change the way in which Slice use is permitted by conditions in fish farm licences. This will allow continued use of the medicine, but subject to tighter restrictions on use. These arrangements are likely to remain in place for a period of two years, allowing the aquaculture sector, or the company which markets Slice, to carry out further research to confirm or confound the apparent link between Slice use and unexpected distribution of residues and possible environmental effects. SEPA will also be undertaking further analysis and monitoring work during this period. If, during the next two years, no compelling case is made to support the continued use of the product, it is likely that the ability to use Slice will be phased out completely.

We have informed fish farm operators of SEPA's position that, unless we see new and compelling evidence to support continued use, the ability to use Slice is likely to be phased out in 2018. We are also working in partnership with the industry, the Scottish Government, the Scottish Aquaculture Innovation Centre and other key partners, to explore the potential for the development of alternative means of controlling sea lice, which minimise the risk to our marine environment. The challenge of controlling sea lice in fish farms is not unique to Scotland, and the research and development of these alternative means represents a significant opportunity for Scotland to establish itself as a leader in the field, and could benefit both the aquaculture sector and Scotland's wider economy in the long run.

A new computer model, created by researchers at the Scottish Association for Marine Science (SAMS), with support from the Scottish Government and SEPA, will become a key tool in the future regulation of fish farms. This model, called NewDEPOMOD, will be available for use in applying for fish farm licences later this year and will enable a better understanding of how discharges from fish farms affect the seabed. NewDEPOMOD will replace the current AutoDEPOMOD model, which has been in use since 1999. SEPA also recently launched a new survey vessel, the Iona, designed specifically to enhance our capability to monitor the environmental impacts of marine fish farms.

We believe that the only businesses which will thrive in the 21st century will be those which have developed ways to prosper within our planet's capacity to support them. These businesses will see improving their environmental performance as an opportunity, not a problem. Our role as a 21st century regulator is to help them to take these opportunities, creating lasting prosperity and viability from the resources of one planet. This will require us to develop our capacity and capability to work with businesses in ways which encourage and support innovative thinking for the 21st century, working collaboratively with business sectors, individual businesses and other organisations to drive and support innovation, problem-solving and, ultimately, prosperity within the capacity of our planet to support it. Our approach to working with Scotland's aquaculture industry, to help turn this environmental challenge into an opportunity to ensure a thriving and sustainable fish-farming sector, is just one example of us putting this approach into practice.

Ends

MARK

Mackinnon, Alison

From: Baird, Stuart
Sent: 10 August 2016 09:37
To: Sinclair, Douglas; MacNaught, Kevin
Cc: Wells, Mark
Subject: RE: SLICE
Attachments: SLICE QA for PAMP report Draft.docx

Sensitivity: Confidential

RR 41

Thanks Douglas,

I've further updated the Q&A document as we had anticipated a few additional questions from the 'wrapper', along the lines of the ones you have posed here. Latest version is attached.

Stuart

From: Sinclair, Douglas
Sent: 10 August 2016 08:58
To: MacNaught, Kevin; Baird, Stuart
Cc: Wells, Mark
Subject: RE: SLICE
Sensitivity: Confidential

RR 40

Hi folks

Some tweaks and "A"s below.

As we discussed, there's probably nothing wrong with such an abbreviated response but it will simply spawn (sorry) more questions which might have been adequate answered by our longer SEPA View narrative. I'd be in favour of getting out whatever we are releasing as soon as the SARF report appears, or before under embargo if that were possible, mainly because I'm not in the office tomorrow, nor on Friday although I can do a couple of hours on Friday as required.

Happy to discuss as required.....

D

SUGGESTED KEY POINTS FOR POSSIBLE PRESS RELEASE –

- **SEPA and the fish-farming sector carry out general monitoring of the overall health of the seabed close to individual fish farms. This monitoring has shown that at a small number of fish farms residues from the use of the sea louse medicine ,Slice are present at levels around or in some cases slightly above the safe environmental standard.**

- **Slice is based on the active ingredient emamectin benzoate and SEPA seeks through the licensing framework to carefully control releases of this substance. This is because emamectin benzoate like all other chemicals used as sea louse medicines may pose a risk to marine life if use is not limited to ensure levels in the environment remain below safe levels.**

- **SEPA invited the Scottish Aquaculture Research Forum (SARF) to commission research to further analyse our data. This analysis identified a subtle but statistically likely, and unexpected, association between impact on the marine environment and the use of**

Slice. This suggests that the environment may not be adequately protected by the current system of regulation for Slice.

- **Where robust evidence suggests that some part of our regulatory regime is not providing the expected and required level of environmental protection, we must take action to reduce or remove the potential for those impacts.**

- **In this case, we are intending to change the way in which Slice use is permitted in fish farm licences. In addition to the change in permitted use, we have informed fish farm operators of SEPA's position that, unless we see new and compelling evidence to support continued use, the ability to use Slice is likely to be phased out over the next two years.**

FURTHER QUESTIONS FOR Q&A

- **SEPA is taking action based on the SARF report. Yet the preamble to the report undermines the content of the report and suggests that further research is required. Why is SEPA taking further action on a report which appears to be highly disputed?**
  While the preamble of the report is critical of various technical aspects of the research work, it does not contradict the main conclusion that there appears to be an association between the use of the sea louse medicine Slice on fish farms and impacts on crustacean populations in the waterbodies where those fish farms are situated.

- **Are there viable and accessible alternatives which the fish farm industry can use instead of SLICE? (this is on the original Q&A but think we need a fuller answer).**
  There are a number of alternative authorised medicines and in addition to these chemical based solutions, there are a number of other methods for louse removal either in development of in use on fish farms in Scotland and internationally. These include the use of "cleaner-fish" such as wrasse and lumpfish. These small fish feed on the sea lice found on farmed salmon thus removing the parasites from the farmed fish. In addition to cleaner-fish, a number of mechanical solutions are available. These include systems using warm water for example the "Thermolicer" see http://www.steinsvik.no/en/products/e/seaculture/fish-health/thermolicer and technology using lasers for example "Stingray" http://en.stingray.no/page/6019/Sea_Lice to remove lice. Slice is currently an important part of the Scottish fish farmers' arsenal in the war against lice and SEPA's proposal is not to immediately remove the product from the marketplace but phase the product out over a timescale which will allow development of these and other alternatives to advance.

- **Is SEPA using the report as an excuse to undermine the fish farm industry?**
  No, SEPA supports the growth and development of a sustainable fish farming sector, however the evidence in this report potentially undermines the sustainability of the sector as it demonstrates a statistically likely link between impacts on the wider environment and the operation of fish farms. SEPA has always accepted and expected that fish farming will have a localised impact on the seabed around the farm but this new evideince suggests a more widespread effect upon the environment.

- **Why is there such a difference in how SEPA appears to be reading the report compared to how fish-farm bodies appear to be reading the report?**
  SEPA accepts the conclusion in the report that there appears to be an association between the use of the sea louse medicine Slice with impacts on the environment. It is SEPA's responsibility to take action where it appears that some element of the regulatory framework is not providing environmental protection. Other bodies involved may not have such a duty.

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I no longer work on Mondays, normally available Tuesday - Friday.
During absences from the office, my e-mails may be read and you may receive a response from Anne Mitchell, Senior Admin Officer in the SEPA Orkney Office.

Consider the environment. Please don't print this e-mail unless you really need to.

From: MacNaught, Kevin
Sent: 09 August 2016 17:30
To: Baird, Stuart; Sinclair, Douglas
Cc: Wells, Mark
Subject: SLICE
Sensitivity: Confidential

Hi Stuart/ Douglas, some suggested key points in case it is decided that a short press release is the course of action.
Also some further questions for Q&A given latest developments below.
Regards,
Kevin

SUGGESTED KEY POINTS FOR POSSIBLE PRESS RELEASE –

- **SEPA and the fish-farming sector carry out general monitoring of the overall health of the seabed close to individual fish farms. This monitoring has shown that at a small number of fish farms residues from the use of Slice are present at levels around or slightly above the safe environmental standard.**

- **SEPA invited the Scottish Aquaculture Research Forum (SARF) to commission research to further analyse our data. This analysis identified a subtle but detectable, and unexpected, association between impact on the marine environment and the use of Slice.**

- **Where robust evidence suggests that some part of our regulatory regime is not providing the expected and required level of environmental protection, we must take action to reduce or remove the potential for those impacts.**

- **In this case, we are intending to change the way in which Slice use is permitted in fish farm licences. We have informed fish farm operators of SEPA's position that, unless we see new and compelling evidence to support continued use, the ability to use Slice is likely to be phased out in 2018.**

FURTHER QUESTIONS FOR Q&A

- **SEPA is taking action based on the SARF report. Yet the preamble to the report undermines the content of the report and suggests that further research is required. Why is SEPA taking further action on a report which appears to be highly disputed?**

- **Are there viable and accessible alternatives which the fish farm industry can use instead of SLICE? (this is on the original Q&A but think we need a fuller answer).**

- **Is SEPA using the report as an excuse to undermine the fish farm industry?**

- **Why is there such a difference in how SEPA appears to be reading the report compared to how fish-farm bodies appear to be reading the report?**

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FR242

SLICE – Q&A

PROTECT – these have been prepared by SEPA. The questions were posed for our research purposes and also to assist with drafting responses to any media enquiries and should not be disseminated/used by any other organisation.

- What impact is SLICE having on the environment and on species?
  SEPA expects that where fish farms are operated and substances such as Slice are used that the environment will be affected. The licensing system we have for farms is however designed to limit these effects to the area around and close to the fish farm cages. This study of the data (PAMP-2 Study) on communities of animals living in the seabed shows a subtle but detectable and unexpected impact on communities of crustaceans in the seabed in waterbodies where there is a history of Slice use. The effect extends beyond the immediate vicinity of the fish farm. This seems to show that at sites where there is a history of Slice use there are fewer different species and fewer actual individual crustaceans compared to sites where it hasn't been used.

- What species have been impacted by these findings? And by what number has their abundance been reduced?
  The indicated effect is limited to crustaceans, mainly small species of animals such as tiny shrimps which live in the seabed sand and mud. The changes in abundance are highly variable depending on where the samples are taken in relation to fish farms and on how often the treatment has been used. On average, sites where Slice treatments have been regularly used over several years will have 81% fewer crustaceans present than sites where the treatment has not been used.

- When (and how) did SEPA become aware of this?
  The Post-Authorisation Monitoring Project containing the evidence was published on 10 August 2016. This was the outcome of a 2 year project which was given by the Scottish Aquaculture Research Forum (SARF) to the Scottish Association for Marine Science (SAMS) to undertake. The project was proposed by SEPA as the Agency is a Director of SARF. SEPA suggested to SARF that the project was worthwhile because:
  a) It was some time since research of this type had been done;
  b) The pattern of use of the product had changed since it was introduced;
  c) There was some discussion, for example with shellfishermen suggesting that unexpected effects were being observed.

- Why didn't SEPA spot this as the Scottish Association for Marine Science did the Post-Authorisation Monitoring Project study using SEPA's data?
  Our assessment of the condition of the seabed doesn't concentrate just on crustaceans but on the chemistry of the seabed and the overall health of the different groups of animals present there. It's a general view of the overall health of the seabed close to fish farms. Normally then, our routine monitoring would not necessarily spot a reduction in the numbers of crustaceans at any individual site and even if this were detected on a site-by-site basis it would not in itself necessarily be indicative of a problem. SEPA collects data on the condition of the seabed around fish farms and holds a great deal of this data. It is the scale of the data held by SEPA that means it is hard to analyse but also gives the information great value. But given the scale of work need to draw meaningful conclusions it is not something that we routinely do and why a 2 year project was required to find this possible link.

- How long does SEPA expect that the indicated impacts may have been happening (before SEPA realised)?
  It is difficult to be certain. When Slice was first introduced in 1999-2000, a 5 year project to assess any impacts was established - the original Post Authorisation Assessment Project [link], its final report was published in 2005. This was a substantial piece of research funded by SEPA and a range of other partners which concluded that there was no discernible impact on the environment from the use of Slice and another sea louse medicine. It seems unlikely that this effect was present at that time as the study would have detected it. Since then, the patterns of use of Slice have changed which may has resulted in the observed effect arising. It's not therefore possible to be certain when such impacts may have arisen but probably sometime within the last 10 years.

- If fish farmers have been using SLICE at levels permitted by SEPA then how can this have happened?
  The amount of Slice that can be used for a treatment at any fish farm is limited by a series of equations. The aim of these equations is to restrict the amount of the medicine that can be used depending on how much might be around in the environment from previous treatments to avoid a build-up of residues and ensure any Slice remaining is at safe levels and that the residues do not last too long. While there is no suggestion that in most cases the safe levels of residues have been exceeded it is possible that changing use has seen an increase in the length of time that residues are present in the seabed. The extended duration of residues being present may have caused the unexpected effect that is indicated by the study of the data (PAMP-2).
  SEPA's own investigations into the dispersion of Emamectin Benzoate in Shuna Sound indicates a wider than expected dispersion of residues and identifies a knowledge gap in SEPA's understanding of this dispersion. From the available data it appears that the sediment to which EmBZ is attached is dispersed over greater distances than that predicted by the model and present method.

- What levels of SLICE would be regarded as safe/ normal in the environment? And what levels of SLICE have actually been found in the environment?
  SEPA sets a limit of 0.763 microgrammes of Slice per kilogram of wet sediment (0.763µg/kg) as a safe environmental standard which should ensure the protection of the environment beyond the vicinity of the fish farm. Data is collected on residue levels in the seabed around fish farms but these samples do not necessarily co-incide with the samples used to work out how many crustaceans are present in the seabed. In any typical year, a small number of farms are shown to have residues present at levels above this safe environmental standard. At this point it is clear that the safe environmental standard has not been breached in a widespread way across waterbodies but that residues have been found to be more widely spread than had been anticipated in some cases. The subtle effects on crustaceans that is indicated by the study is most likely being seen at concentrations below the safe environmental standard.

- What action is SEPA taking to rectify this situation?
  SEPA takes this matter very seriously. We are an evidence based regulator and where there is robust evidence that some part of our regulatory regime is not providing environmental protection we will take steps to reduce or remove the potential for impacts. In this case having developed concerns about the use of Slice, SEPA sought that research be undertaken to assess whether there were subtle impacts. This report is the outcome of that research and SEPA intends to take the following steps to rectify the situation:

a) *Further restrict the use of the medicine to limit the potential for repetitive use and overuse of the product at fish farms.*
b) *Undertake further analysis and monitoring work to increase our understanding of the possible impacts that are indicated in the PAMP-2 study.*
c) *Review the Environmental Standard that has been set for the residues of Slice in the marine environment to update these*
d) *Work with the sector or the company which markets SLICE as they carry out further research to confirm or confound the apparent link between SLICE use and unexpected environmental effects*
e) *If during the next two years no compelling case is made to support the continued use of the product, authorisations for the use and discharge of SLICE will be withdrawn by SEPA.*

- Is there a definitive date when fish farms will no longer be able to legally use SLICE?
  There is no firm date but if during the next two years no compelling case is made to support the continued use of the product, authorisations for the use and discharge of SLICE will be withdrawn by SEPA.

- Should SEPA withdraw its use, could fish farms not just import SLICE and use it anyway?
  The importation of medicines is not something that SEPA regulates but were Slice to be used and released from a fish farm when it is no longer authorised by SEPA such use would be illegal.

- What action will SEPA take against fish farms which continue to use SLICE if authorisation for its use has been withdrawn?
  The use and discharge of substances that are not authorised by conditions in CAR licences is illegal. Deliberate unauthorised releases of substances posing a significant environmental threat would normally be a matter dealt with under SEPA's Enforcement Policy.

- Are there viable and accessible alternatives which the fish farm industry can use instead of SLICE?
  There are a number of alternative authorised medicines (Current fish farm licences already include the use of bath treatments using approved chemicals such as azamethiphos (trade name Salmosan), cypermethrin (Excis), deltamethrin (AMX) and hydrogen peroxide) and in addition to these chemical based solutions, there are a number of other methods for louse removal either in development of in use on fish farms in Scotland and internationally. These include the use of "cleaner-fish" such as wrasse and lumpfish. These small fish feed on the sea lice found on farmed salmon thus removing the parasites from the farmed fish. In addition to cleaner-fish, a number of mechanical solutions are available. These include systems using warm water for example the "Thermolicer" see http://www.steinsvik.no/en/products/e/seaculture/fish-health/thermolicer and technology using lasers for example "Stingray" http://en.stingray.no/page/6019/Sea_Lice to remove lice. Slice is currently an important part of the Scottish fish farmers' arsenal in the war against lice and SEPA's proposal is not to immediately remove the product from the marketplace but phase the product out over a timescale which will allow development of these and other alternatives to advance.

- Only a few months ago the fish farm industry was instructed not to use teflubenzuron. Now you are instructing fish farms not to use SLICE when you had previously stated

it was safe to use. Do these findings undermine SEPA's reputation as an effective regulator of fish farms?
Effective environmental regulation is about using scientific evidence to assess the impacts of development and activities on the environment and using the regulatory framework to allow development and use of the environment where possible but to ensure that the impacts of such are within acceptable boundaries. The licensing of fish farms, including licensing the release of sea louse medicines is based around series of complex scientific assessments. At the time that these assessments were developed on the best available science and subject to independent review, they suggested that adequate environmental protection would be provided. Subsequent assessment of the impacts of the use of Calicide and Slice upon the environment has indicated higher than anticipated levels of residues (in the former case) and subtle unexpected impacts in the case of Slice.

- How many fish farms have used SLICE (e.g. in the last 2 years)? Where are these fish farms located?
  The product was used at 148 sites in 2014 and 133 sites in 2015 [SPRI ART sites] The farms are located in a wide variety of locations on the West coast, the Western Isles and Shetland.

- I'm confused because the Compliance Assessment Scheme results for 2014 indicate that many fish farms have performed very well. Given the findings regarding SLICE – why is this?
  The assessments undertaken in CAS are a site specific view of the performance of individual sites. This study is a widespread statistical assessment of the subtle effects of Slice on the environment rather than a measure of the way each site performs. The Compliance Assessment Scheme would not normally pick up the subtle effects reported in the PAMP-2 study.

- Is SEPA certain that any fish farm medicines are safe to use? Why should we believe that SEPA won't backtrack on its view on other fish farm medicines in the future?
  SEPA will continue to review its position on all elements of fish farm regulation and if required will improve the means by which the regulation of fish farms is undertaken. We have no reason to believe that our position on other fish farm medicines will change in the near future.

- Should there be a moratorium on the use of all fish farm medicines until you can be confident that they are not having unexpected impacts?
  No, but if evidence suggests or demonstrates that the fate and behaviour when released into the water environment of any particular product is not safe or is different to that which had been predicted, then SEPA will take appropriate action to investigate and resolve the matter, which might involve the cessation of use.

- We got tipped off on these developments by the industry. Why has SEPA not proactively kept the public informed of these developments? Is SEPA in cahoots with SLICE manufacturers/ marketers?
  No, SEPA is not in cahoots with manufacturers of medicines or those who market such products.

The preamble/ wrapper (cover note) to SARF098: Towards understanding of the Environmental Impact of a Sea Lice Medicine – the PAMP suite raises a number of concerns in relation to the PAMP-2 study

- SEPA is taking action based on the SARF report. Yet the preamble to the report undermines the content of the report and suggests that further research is required. Why is SEPA taking further action on a report which appears to be highly disputed?
While the preamble of the report is critical of various technical aspects of the research work, it does not contradict the main conclusion that there appears to be an association between the use of the sea louse medicine Slice on fish farms and impacts on crustacean populations in the waterbodies where those fish farms are situated.

- Is SEPA using the report as an excuse to undermine the fish farm industry?
No, SEPA supports the growth and development of a sustainable fish farming sector, however the evidence in this report potentially undermines the sustainability of the sector as it demonstrates a statistically likely link between impacts on the wider environment and the operation of fish farms. SEPA has always accepted and expected that fish farming will have a localised impact on the seabed around the farm but this new evideince suggests a more widespread effect upon the environment.

- Why is there such a difference in how SEPA appears to be reading the report compared to how fish-farm bodies appear to be reading the report?
SEPA accepts the conclusion in the report that there appears to be an association between the use of the sea louse medicine Slice with impacts on the environment. It is SEPA's responsibility to take action where it appears that some element of the regulatory framework is not providing environmental protection. Other bodies involved may not have such a duty.

- The need for future clarification of NOEL, LOQ & LOD and the development of clearer analytical methods for Emamectin Benzoate are identified in the preamble/wrapper. What is SEPA doing about this?

Analytical terms
Guidance is available for the understanding of the analytical terms LOD (which is often mixed interchangeably with MDL) and LOQ. However, when the LOD is quoted, it is usually the MDL that is actually provided as in this instance it takes account of the recovery from the sediment matrix. This can indeed lead to some confusion. Where laboratories operate under ISO17025 accreditation the procedures for reporting data from the analysis they undertake and their adherence to them are independently audited by UKAS.
The simple definitions for each are:
- *LOD or Limit of Detection is the value (concentration) above which it can be affirmed with a stated level of (statistical) confidence that a sample is different from a blank sample (ie. a sample containing no determined of interest).*
- *MDL or Method Detection Limit is the value (concentration) above which it can be affirmed with a stated level of (statistical) confidence that a sample is different from a blank sample taking into account correction for recovery and any dilution (ie. it works out the limit for detection in a real sample matrix that has gone through the extraction and analytical process).*
- *LOQ or Limit of Quanitifcation is a (stated) multiple of the LOD at a concentration of the determined of interest that can reasonably be determined with an accurate level of accuracy and precision. The LOQ can be calculated using an appropriate standard or sample.*

Toxicity terms

NOEL – is the No Observable Effects Level, - this is a highest value (concentration) of a substance, found by experiment or observation, that causes no alterations of morphology, functional capacity, growth, development, or life span of target organisms distinguishable from those observed in normal (control) organisms of the same species and strain under the same defined conditions of exposure.

Toxicity in an organism requires it to be exposed to a substance that elicits a toxic effect, this is sometimes more simply expressed as harm is caused by hazard plus exposure.

"Basic tenets of toxicology…. where toxicity is regarded as a threshold response" This statement is inaccurate. Although for many substances the classic linear or threshold models of toxicity are still thought to apply much of that knowledge has come from short-term, gross effects tests that focus at higher concentrations. There are a number of general toxicity models now accepted, for example there are linear, threshold, bi-phasic and multi-phasic response models. Evidence is increasing that exposure at low level doses of some substances does not conform to the non-linear and non-threshold response models. In particular the evidence is increasing for substances with "endocrine" effects, where reports of bi-phasic and multi-phasic responses at low and ultra-low doses are being reported. Whether these models of toxicity apply to this active ingredient is unclear.

Where are we with the review of the current Regulatory Standard?

SEPA will shortly be commissioning a review of the current regulatory standard for emamectin benzoate residues. The derivation of the updated standard will adhere to the Water Framework Directive methodologies for the derivation of Environmental Quality Standards have been updated (Common Implementation Strategy for the Water Framework Directive (2000/60/EC) Guidance Document No. 27 Technical Guidance For Deriving Environmental Quality Standard). As part of the review a literature search will be undertaken to identify any data published since the original standard was derived and will consider changes to the pattern of use since the standard was derived.

- Comment that some reviewers regard the investigation as one that is unsuitable for direct use in evidence-based regulation, but one that is indicative of an issue that deserves more rigorous investigation. Why has SEPA used the results of the investigation to inform its regulatory response when it is unsuitable for such use?

  In taking a position in relation to the ongoing regulation of the use and discharge of Slice at fish farms SEPA has taken into account its own research (Shuna Sound), the PAMP-2 study, reviewers comments on the study, the preamble/wrapper and has consulted with the Industry and manufacturers on the proposed course of action. Our regulatory position has been informed by the interests both of the industry and others who have an interest in the marine environment and is based upon an assessment of the available evidence from the studies and the risks and issues identified by these. We believe that the approach, which allows continued but more controlled use while further research is undertaken to confirm or confound the issues that have been raised by the studies is proportionate and appropriately takes into account these interests.

- Comment that more research is needed before contemplating action relating to marine management policy, strategy or implementation. How can SEPA justify taking action before further research is completed?

Our position of allowing the continued use of Slice for a period of two years allows further research to be undertaken to confirm or confound the issues that have been identified by the studies. This research, together with work on the clarification/review of the environmental standard will be important in determining the regulatory response which SEPA takes.

- Standardisation of sampling procedure for future work to assess the effects of emamectin benzoate is recommended by the PAMP-2 report, what is SEPA doing in response to this?

  SEPA is discussing proposals for future monitoring with industry representatives to ensure that common methodologies and techniques are used wherever it is practicable to do so.